

Designation Run Report

# Prevoznik, Thomas - Plaintiffs' Submission

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Prevoznik, Thomas 04-17-2019  
Prevoznik, Thomas 04-18-2019  
Prevoznik, Thomas 05-17-2019

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**Plaintiff Affirmatives 02:05:49**

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**Defense Completeness Counters 00:02:38**

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**Total Time 02:08:28**



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
41:21 - 42:04	<b>Prevoznik, Thomas 04-17-2019 (00:00:14)</b> 41:21 Q. As I understand it, you 41:22 currently work for DEA; is that correct? 41:23 A. Yes. 41:24 Q. And what is your position? 42:1 A. I am currently the acting 42:2 section chief of the pharmaceutical 42:3 investigations in the diversion control 42:4 division.	TP01.1
42:11 - 43:18	<b>Prevoznik, Thomas 04-17-2019 (00:01:36)</b> 42:11 And in -- how long have you 42:12 had that position? 42:13 A. I've been acting since 42:14 mid-January of this year. 42:15 Q. How long have you been at 42:16 DEA overall? 42:17 A. Over 28 years. 42:18 Q. And is it fair to say that 42:19 part of the time that you were at DEA, 42:20 you were in the field, one of the field 42:21 offices, or several field offices, and 42:22 part of the time you've been at DEA 42:23 you've been at corporate headquarters? 42:24 A. I've been in the field. 43:1 I've been in our training academy as an 43:2 instructor, and I've also went back to 43:3 the field, and then to headquarters. 43:4 Q. Your current position is at 43:5 headquarters, correct? 43:6 A. Correct. 43:7 Q. And what -- in that 43:8 position, do you have any oversight or 43:9 responsibility related to suspicious 43:10 order monitoring or reporting? 43:11 A. Yes. My -- well, they just 43:12 split our unit, our section to a -- so 43:13 that analytics side, which was ARCOS, 43:14 which includes drug theft loss, and SORs 43:15 data, the output side. They've been 43:16 moved to another section. That was like	TP01.2

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59:07 - 59:19	<p>43:17 two weeks ago. But prior to that it'd 43:18 been under -- under me.</p> <p><b>Prevoznik, Thomas 04-17-2019 (00:00:28)</b></p> <p>59:7 Q. Now, prior to your current 59:8 title, which is section chief of 59:9 pharmaceutical investigations, you were 59:10 the unit chief in the same section; is 59:11 that right? 59:12 A. No. So in January 2017, I 59:13 got promoted to the associate section 59:14 chief up in pharmaceutical 59:15 investigations. 59:16 Prior to that I was the unit 59:17 chief down in our policy and liaison 59:18 section. But I was the unit chief over 59:19 liaison.</p>	TP01.3
59:24 - 60:19	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:53)</b></p> <p>59:24 Can you just again describe 60:1 for me at a high level what the purpose 60:2 of the unit is or the primary goals of 60:3 the unit? 60:4 A. Well, I mean, what I did was 60:5 I coordinated conferences, whether it was 60:6 the pharmacy diversion awareness 60:7 conferences. I gave a lot of 60:8 presentations. We would have to -- we 60:9 would coordinate with various entities to 60:10 try to get continuing education credits 60:11 for the pharmacists, and the techs. We 60:12 would do the DEA general conference -- 60:13 conferences. You know, the distributor 60:14 conference. We would help our quota unit 60:15 with setting up the manufacturing 60:16 training that they would do. 60:17 I mean, we were like the 60:18 spokespeople, as well as coordinating the 60:19 events themselves.</p>	TP01.4
62:07 - 62:17	<p><b>Prevoznik, Thomas 04-17-2019 (00:00:33)</b></p> <p>62:7 Q. Let me ask it this way. 62:8 The liaison unit, what</p>	TP01.5

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	62:9 interaction did the liaison unit have 62:10 with suspicious order monitoring or 62:11 reporting? 62:12 A. I mean, at the conferences, 62:13 I mean, I gave presentations in 2013 and 62:14 '15 to the distributor -- at the 62:15 distributor conferences. So, I mean, I 62:16 know I talked about suspicious orders. I 62:17 talked about thresholds.	
63:21 - 64:06	<b>Prevoznik, Thomas 04-17-2019 (00:00:18)</b> 63:21 Q. And did you present at the 63:22 most recent one? 63:23 A. No. I did the '13 and '15. 63:24 Q. You presented at the '13 and 64:1 '15. 64:2 Now, prior to -- as part of 64:3 your preparation, did you come to learn 64:4 of prior distributor conferences that 64:5 took place? 64:6 A. Yes. Mm-hmm.	TP01.6
64:07 - 64:18	<b>Prevoznik, Thomas 04-17-2019 (00:00:28)</b> 64:7 Q. Do you recall just 64:8 approximately what years the other 64:9 distributor conferences were, just 64:10 approximately? 64:11 A. No. The distributor 64:12 conference became more unique around the 64:13 time that we did it. But before that it 64:14 was when they were actually together. It 64:15 was like an industry conference. And 64:16 that was -- that was more frequent, I 64:17 believe. I don't have a time frame for 64:18 you.	TP01.7
71:04 - 71:08	<b>Prevoznik, Thomas 04-17-2019 (00:00:13)</b> 71:4 Unless I say otherwise, when 71:5 I say you, or the DEA, or the 71:6 administration, I'm generally referring 71:7 to the entity that is the Drug 71:8 Enforcement Administration.	TP01.8
84:02 - 84:21	<b>Prevoznik, Thomas 04-17-2019 (00:00:38)</b>	TP01.9

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84:2 Q. You're always a diversion

84:3 investigator?

84:4 A. Yes, I've been one for

84:5 28 years.

84:6 Q. Okay. Your primary

84:7 responsibilities, you were no longer

84:8 primarily operating as a diversion

84:9 investigator after December 2008, fair?

84:10 A. When I became the

84:11 supervisor?

84:12 Q. Yes. As a supervisor, did

84:13 you continue to function as a diversion

84:14 investigator as a primary part of what

84:15 you were doing?

84:16 A. Not as primary.

84:17 Q. But sometimes as a

84:18 general -- in terms of the supervision of

84:19 investigators, you would provide advice

84:20 and guidance on what they ought to do?

84:21 A. Correct.

86:16 - 87:02

**Prevoznik, Thomas 04-17-2019 (00:00:17)**

TP01.10

86:16 What areas did you train in,

86:17 was it primarily diversion control?

86:18 A. It was all diversion

86:19 control.

86:20 Q. All diversion control?

86:21 A. Yeah, I mean I would assist

86:22 with some of the special agent stuff,

86:23 but...

86:24 Q. How much training do

87:1 diversion investigators as a general

87:2 matter get?

87:05 - 87:06

**Prevoznik, Thomas 04-17-2019 (00:00:03)**

TP01.11

87:5 THE WITNESS: It's 12 weeks.

87:6 The training at Quantico.

87:08 - 87:11

**Prevoznik, Thomas 04-17-2019 (00:00:09)**

TP01.12

87:8 Q. All on diversion control?

87:9 A. Correct.

87:10 Q. And what are the components

87:11 of that training at a high level?

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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87:16 - 88:21	<p><b>Prevoznik, Thomas 04-17-2019 (00:01:24)</b></p> <p>87:16 THE WITNESS: So it would be  87:17 the -- the law, we would have law.  87:18 You would have the record  87:19 requirements. It would be  87:20 interviewing. It would be audits.  87:21 Like reviewing records for  87:22 pharmacy audit. Reviewing records  87:23 for distributor audit. Reviewing  87:24 records for a manufacturing audit.  88:1 Ethics training. Just a lot of  88:2 interviewing, practicals. We did  88:3 various practicals as well, just  88:4 to give them like a real life --  88:5 try to give them a real life  88:6 experience as best we could.  88:7 BY MS. MAINIGI:  88:8 Q. And after the initial  88:9 12-week training, are there any refresher  88:10 courses that are -- or refresher training  88:11 that is provided to diversion  88:12 investigators?  88:13 A. Yes, there is --  88:14 Q. How often is that?  88:15 A. It depends. Each -- it --  88:16 it's typically within three to  88:17 five years.  88:18 Q. And how long is the  88:19 refresher training?  88:20 A. I believe it was about a  88:21 week.</p>	TP01.13
597:06 - 598:10	<p><b>Prevoznik, Thomas 04-18-2019 (00:01:11)</b></p> <p>597:6 Q. Will you state your name,  597:7 rank, and title?  597:8 A. Thomas Prevoznik. I am the  597:9 acting section chief of pharmaceutical  597:10 investigations for the DEA's diversion  597:11 control division.  597:12 Q. Mr. Prevoznik, my name is  597:13 Paul Farrell, and I am one of the lawyers</p>	TP01.14

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597:14 representing the plaintiffs. And so I  
 597:15 thank you for coming here today. And I  
 597:16 just wanted to set for the record, we  
 597:17 sent a list of subject matters to the  
 597:18 United States Drug Enforcement Agency and  
 597:19 asked for somebody to be designated to  
 597:20 testify on its behalf.

597:21 You understand that the  
 597:22 questions that I ask you today are not in  
 597:23 your individual capacity, but we're  
 597:24 asking for answers as if it was coming  
 598:1 from the DEA itself.

598:2 A. Correct.

598:3 Q. So the million-dollar  
 598:4 question right out of the gate is, why  
 598:5 didn't the DEA do more?

598:6 So what I want to do is, I  
 598:7 have the testimony from the former acting  
 598:8 administrator, Robert Patterson. And I'm  
 598:9 going to show you a video clip and then  
 598:10 ask some follow-up questions. Okay?

598:12 - 599:06

**Prevoznik, Thomas 04-18-2019 (00:00:35)**

TP01.15

598:12 THE WITNESS: Okay.

598:13 MR. FARRELL: 523.

598:14 BY MR. FARRELL:

598:15 Q. This is Mr. Patterson's  
 598:16 opening statement I believe his testimony  
 598:17 before Congress on March 20, 2018, in  
 598:18 front of the subcommittee on oversight  
 598:19 and investigations, the committee on  
 598:20 Energy and Commerce.

598:21 You're aware that  
 598:22 Mr. Patterson testified?

598:23 A. Yes.

598:24 Q. And he testified on behalf  
 599:1 of the DEA?

599:2 A. Yes.

599:3 Q. To Congress under oath?

599:4 A. Yes.

599:5 MR. FARRELL: Show the first

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599:07 - 601:20

599:6 clip, please.

**Prevoznik, Thomas 04-18-2019 (00:02:06)**

TP01.16

599:7 (Video clip played as

599:8 follows:)

599:9 MR. PATTERSON: Where

599:10 license revocation is not

599:11 necessary, we've aggressively

599:12 pursued civil actions and MOUs

599:13 designed to ensure compliance.

599:14 Over the last decade, DEA has

599:15 levied fines totalling nearly

599:16 \$390 million against opioid

599:17 distributors nationwide and

599:18 entered into MOUs with each.

599:19 (Video concluded.)

599:20 BY MR. FARRELL:

599:21 Q. Mr. Prevoznik, can you

599:22 verify the accuracy of that statement?

599:23 A. Yes.

599:24 Q. So the DEA has in fact

600:1 attempted to impose civil penalties and

600:2 conducted investigations into opioid

600:3 distribution and diversion?

600:4 A. Correct.

600:5 Q. I'm going to go to the next

600:6 clip. This is where the follow-up really

600:7 begins.

600:8 (Video clip played as

600:9 follows:)

600:10 MR. PATTERSON:

600:11 Administrative actions, civil

600:12 fines, and criminal cases are all

600:13 important steps. Where we have

600:14 fallen short in the past, it is by

600:15 not proactively leveraging the

600:16 data that has been available to

600:17 us.

600:18 (Video concluded.)

600:19 BY MR. FARRELL:

600:20 Q. Mr. Prevoznik, are you



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600:21 familiar with that complaint?

600:22 A. Yes.

600:23 Q. I'm also going to show you

600:24 what has been previously referenced in

601:1 this trial, the jury has heard probably

601:2 several times, is the Energy and

601:3 Commerce's report following the testimony

601:4 of Mr. Patterson as well as the testimony

601:5 from numerous others.

601:6 Are you familiar with this

601:7 report?

601:8 A. Yes, I am.

601:9 Q. And this is on one

601:10 particular page, one of the findings and

601:11 the markings up are the lawyers, not from

601:12 Congress. You'll see where I put the

601:13 Star. And it basically says, "Had

601:14 HDA" -- "Had DEA more proactively used

601:15 ARCOS data, it could have discovered, in

601:16 a period of time at a place called

601:17 Sav-Rite Pharmacy Number 1 that there

601:18 were a lot of pills that were shipped."

601:19 Are you familiar with this

601:20 finding from Congress?

601:22 - 601:22 **Prevoznik, Thomas 04-18-2019 (00:00:01)**

TP01.17

601:22 THE WITNESS: Yes.

601:23 - 603:15 **Prevoznik, Thomas 04-18-2019 (00:01:48)**

TP01.18

601:23 BY MR. FARRELL:

601:24 Q. So when you and I walk

602:1 through the ARCOS data, what we're

602:2 talking about is this dataset of

602:3 information that you had, correct?

602:4 A. Correct.

602:5 Q. And these are transactions

602:6 between manufacturers and distributors,

602:7 between distributors and pharmacies, that

602:8 are stored in a large database maintained

602:9 by the DEA?

602:10 A. Correct.

602:11 Q. Okay. So what -- what does

602:12 it mean when the DEA's position is that  
 602:13 you are not proactively using the ARCOS  
 602:14 data during this time frame?  
 602:15 A. Well, back during that time  
 602:16 frame, we were on what we called the  
 602:17 mainframe. So the process was slower of  
 602:18 ARCOS data, so when it would be uploaded  
 602:19 and processed. And so we were months  
 602:20 behind on getting that data up into the  
 602:21 system.  
 602:22 It was -- we were restricted  
 602:23 to a million transactions of upload per  
 602:24 night. And we received millions of  
 603:1 transactions. So that took a while.  
 603:2 In addition to that, you  
 603:3 also had, when they uploaded, there would  
 603:4 be errors, the most typical errors would  
 603:5 be wrong NDC code, wrong DEA number, or  
 603:6 the wrong DEA 222 order form number.  
 603:7 Q. It's my understanding that  
 603:8 today these transactions are stored  
 603:9 digitally with the DEA ARCOS database; is  
 603:10 that correct?  
 603:11 A. Correct.  
 603:12 Q. And now we are able to  
 603:13 presently and retrospectively look back  
 603:14 and figure out what happened. Is that  
 603:15 fair?

603:21 - 604:08

**Prevoznik, Thomas 04-18-2019 (00:00:28)**

TP01.19

603:21 THE WITNESS: Yes.

603:22 BY MR. FARRELL:

603:23 Q. Okay. Now, this may be a  
 603:24 terrible analogy, but my mind, what I'm  
 604:1 thinking is, just like -- let's say if  
 604:2 the NSA keeps a log of everybody's cell  
 604:3 phone calls in the country, they're not  
 604:4 actively listening to everyone's call,  
 604:5 but they have the ability to go backwards  
 604:6 and piece together what happened. Is  
 604:7 that similar to what the DEA was doing

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604:11 - 604:11	604:8 with ARCOS? <b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.20
604:13 - 604:21	604:11 THE WITNESS: Yes. <b>Prevoznik, Thomas 04-18-2019 (00:00:22)</b> 604:13 Q. Same thing with the SEC. 604:14 There are billions of trades that happen 604:15 on Wall Street, but the SEC isn't 604:16 necessarily the clearinghouse for these 604:17 trades, but it has the capacity to look 604:18 on a computer backwards and figure out 604:19 what happened if somebody broke the law. 604:20 Is that akin to what is going on with the 604:21 DEA and ARCOS during this time frame?	TP01.21
605:01 - 605:24	<b>Prevoznik, Thomas 04-18-2019 (00:00:55)</b> 605:1 THE WITNESS: Yes. 605:2 BY MR. FARRELL: 605:3 Q. So going back and looking 605:4 backwards from this very same energy and 605:5 commerce report, I happened to be 605:6 familiar with it because of the West -- 605:7 because of West Virginia. The Sav-Rite 605:8 Pharmacy from Page 125, Congress went 605:9 back and looked at the old ARCOS data. 605:10 And from it, what it's determined was 605:11 that McKesson Corporation -- are you 605:12 familiar with the company called 605:13 McKesson? 605:14 A. Yes, I am. 605:15 Q. And who are they? 605:16 A. They are a wholesaler, 605:17 distributor. 605:18 Q. McKesson Corporation sold 605:19 five million doses in 2006 and 2007 of 605:20 opium pills to a pharmacy in Kermit, West 605:21 Virginia. Can you, by looking at this 605:22 exhibit, tell me how many people, 605:23 according to Congress, live in Kermit, 605:24 West Virginia?	TP01.22
606:06 - 606:06	<b>Prevoznik, Thomas 04-18-2019 (00:00:02)</b> 606:6 THE WITNESS: 406.	TP01.23

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607:01 - 607:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:14)</b>	TP01.24
607:1	Q. Is there any basis	
607:2	that you can make up in reality or	
607:3	otherwise where a town of 400 people have	
607:4	a medical need for five million pills of	
607:5	opium in a span of 24 months?	
607:09 - 607:13	<b>Prevoznik, Thomas 04-18-2019 (00:00:05)</b>	TP01.25
607:9	THE WITNESS: Correct.	
607:10	There isn't. There isn't.	
607:11	BY MR. FARRELL:	
607:12	Q. There is absolutely no way,	
607:13	is there?	
607:16 - 607:16	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.26
607:16	THE WITNESS: No.	
609:14 - 610:17	<b>Prevoznik, Thomas 04-18-2019 (00:01:01)</b>	TP01.27
609:14	Q. Beyond the opening statement	
609:15	from the DEA to Congress through	
609:16	Mr. Patterson here, there were also	
609:17	questions and answers.	
609:18	So one of the questions	
609:19	Congress asked the DEA was: Why did the	
609:20	DEA communications with industry fail to	
609:21	prevent the kinds of major breakdowns	
609:22	apparent in West Virginia?	
609:23	I'm going to play for you	
609:24	Mr. Patterson's response.	
610:1	(Video clip played as	
610:2	follows:)	
610:3	ROBERT PATTERSON: I think	
610:4	when you go back to that time	
610:5	frame on the suspicious orders	
610:6	reports, there was two major	
610:7	failures. One was either a lack	
610:8	of information contained therein,	
610:9	or not filing them in -- in this	
610:10	instance that they had. I think	
610:11	that started the problem, quite	
610:12	frankly, and a lot of the	
610:13	frustration came from chasing down	
610:14	the registrants and ultimately	

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610:15 reminding them of their 610:16 responsibility in this regulated 610:17 area.		
612:20 - 613:03	<b>Prevoznik, Thomas 04-18-2019 (00:00:15)</b> 612:20 Q. Okay. Back on -- back on 612:21 the questions. 612:22 My question to you is, who 612:23 is the DEA referencing when they are 612:24 talking about chasing down registrants. 613:1 Are we talking about the 613:2 wholesale distributors? 613:3 A. Yes.	TP01.28
613:07 - 613:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:14)</b> 613:7 Q. And then it says that the 613:8 DEA was -- part of their frustration was 613:9 having to chase down the registrants and 613:10 remind them of their responsibilities. 613:11 Can you explain what that 613:12 means? 613:13 What does the DEA mean when 613:14 it says this to Congress?	TP01.29
613:17 - 613:24	<b>Prevoznik, Thomas 04-18-2019 (00:00:20)</b> 613:17 THE WITNESS: It means that 613:18 we, with our letters in 2006, we 613:19 were reiterating what their 613:20 responsibility was to report 613:21 suspicious orders. They may 613:22 needed to -- that the registrants 613:23 needed to meet effective controls 613:24 to guard against diversion.	TP01.30
615:01 - 615:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:14)</b> 615:1 Q. Was it the DEA's assessment 615:2 during the time frame of 2006 and 2007 615:3 that the wholesale distributors, as an 615:4 industry, were not complying with their 615:5 regulatory duties?	TP01.31
615:08 - 616:14	<b>Prevoznik, Thomas 04-18-2019 (00:01:01)</b> 615:8 THE WITNESS: Correct. 615:9 BY MR. FARRELL: 615:10 Q. Now, we're going to go to	TP01.32

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615:11 the next clip.  
 615:12 The follow-up with the DEA  
 615:13 is that a congressman asked the DEA about  
 615:14 the settlements with industry in the  
 615:15 past. And asked them why the past  
 615:16 settlements were not effective in  
 615:17 achieving compliance.  
 615:18 Here is Mr. Patterson's  
 615:19 response on behalf of the DEA.  
 615:20 (Video clip played as  
 615:21 follows:)  
 615:22 ROBERT PATTERSON: And  
 615:23 again, this goes back to the  
 615:24 frustration of the day. And I  
 616:1 know that the -- the folks that  
 616:2 were in diversion back in 2010 and  
 616:3 2012 struggled with the fact that  
 616:4 these MOU or MOAs had been put in  
 616:5 place with these companies and  
 616:6 they blatantly violated them  
 616:7 again.  
 616:8 (Video concluded.)  
 616:9 BY MR. FARRELL:  
 616:10 Q. So my question to you is, is  
 616:11 what can the DEA do if the civil  
 616:12 penalties that they are imposing are not  
 616:13 prohibitive or do not cause the wholesale  
 616:14 distributors to change their conduct?

616:19 - 617:04

**Prevoznik, Thomas 04-18-2019 (00:00:21)**

TP01.33

616:19 THE WITNESS: Okay. We  
 616:20 could take -- we could file an  
 616:21 order to show cause on them. If  
 616:22 we could show imminent danger to  
 616:23 the public, we could file an ISO  
 616:24 against them. We could perhaps  
 617:1 take other civil action or an  
 617:2 injunctive action against the  
 617:3 company, or we could criminally  
 617:4 prosecute.

621:05 - 621:20

**Prevoznik, Thomas 04-18-2019 (00:00:38)**

TP01.34

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	621:5 So the last question that 621:6 was pending and answered, I asked: "Was 621:7 the DEA in fact frustrated that 621:8 registrants were blatantly violating the 621:9 MOUs from prior administrative actions?" 621:10 And your answer was: "Yes." 621:11 There were appropriate 621:12 objections that were made that will be 621:13 resolved one day in the future. So 621:14 here's where my follow-up questions 621:15 comes. 621:16 A. Okay. 621:17 Q. Does that include Cardinal 621:18 Health's 2008 MOU and settlement which 621:19 resulted in a second DEA fine? 621:20 A. Yes.	
624:13 - 624:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b> 624:13 Q. Does that include McKesson's 624:14 2008 MOU and settlement which resulted in 624:15 a second DEA fine?	TP01.35
624:18 - 624:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 624:18 THE WITNESS: Yes.	TP01.36
625:02 - 625:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:13)</b> 625:2 Q. Acting Administrator Robert 625:3 Patterson testified that the DEA has 625:4 1,500 people to monitor 1.73 million 625:5 registrants. Is that an accurate number?	TP01.37
625:08 - 625:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 625:8 THE WITNESS: Yes.	TP01.38
628:12 - 629:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:59)</b> 628:12 Q. So specifically what 628:13 I'm referencing is Cardinal Health's 628:14 reply brief, in Cardinal Health versus 628:15 Eric Holder, which was a preliminary 628:16 injunction filed by Cardinal Health in a 628:17 DC District Court. And in it -- in the 628:18 reply brief there's a provision in here 628:19 that I read to you. And in essence what 628:20 it says is that if you get a suspicious 628:21 order, and you block it, that Cardinal	TP01.39

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	628:22 Health would terminate that customer and 628:23 not sell to it anymore. 628:24 Do you agree that if a 629:1 wholesale distributor gets a flag of a 629:2 suspicious order, that they've determined 629:3 to be a suspicious order, and that they 629:4 block that shipment, that they should 629:5 terminate all future sales to that same 629:6 customer until they can rule out that 629:7 diversion is occurring?	
629:14 - 630:13	<b>Prevoznik, Thomas 04-18-2019 (00:01:14)</b> 629:14 THE WITNESS: Yes, I would 629:15 agree. 629:16 BY MR. FARRELL: 629:17 Q. The same thing applies to a 629:18 document involving McKesson. 629:19 On August 13, 2014, the 629:20 United States Department of Justice was 629:21 communicating with the lawyer for 629:22 McKesson which ended up resulting in a 629:23 \$150 million fine. 629:24 And in this discussion, the 630:1 DEA notes, and I'm reading from Bates 630:2 Stamp MCKMDL 00409224, that the McKesson 630:3 operations manual says the following 630:4 quote: 630:5 "Once McKesson deems an 630:6 order and/or a customer suspicious, 630:7 McKesson is required to act. This means 630:8 all controlled substance sales to that 630:9 customer must cease and the DEA must be 630:10 notified." 630:11 Does the DEA agree with 630:12 those duties? 630:13 A. Yes.	TP01.40
632:05 - 632:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:23)</b> 632:5 Q. So, cleaning up a couple of 632:6 other things. 632:7 There was some testimony 632:8 yesterday, or today actually, from my	TP01.41



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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632:9	learned colleague, that 1.2 million	
632:10	suspicious orders were reported to the	
632:11	DEA between 2007 and 2018.	
632:12	Do you recall that	
632:13	testimony?	
632:14	A. Yes.	
632:17 - 632:19	<b>Prevoznik, Thomas 04-18-2019 (00:00:05)</b>	TP01.42
632:17	Q. If those suspicious orders	
632:18	were filled, is that a, per se, violation	
632:19	of federal law?	
632:22 - 632:22	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.43
632:22	THE WITNESS: Yes.	
633:04 - 633:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:11)</b>	TP01.44
633:4	Q. The foundation of our	
633:5	democracy arises out of the U.S. code.	
633:6	So I'm going to ask a couple of general	
633:7	questions about some code provisions that	
633:8	I'm sure you're very familiar with.	
633:12 - 633:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b>	TP01.45
633:12	Q. The first one is the statute	
633:13	of United States Code Section 801. And I	
633:14	ask for it to be shown on the screen.	
633:15 - 634:01	<b>Prevoznik, Thomas 04-18-2019 (00:00:26)</b>	TP01.46
633:15	So you've been asked in the	
633:16	past, with the focus on Subparagraph 1,	
633:17	that many of the controlled substances	
633:18	that are distributed in America,	
633:19	prescribed and dispensed, have a useful	
633:20	and legitimate medical purpose and that	
633:21	they are necessary to maintain the health	
633:22	and general welfare of the American	
633:23	people.	
633:24	That's a true statement, is	
634:1	it not?	
634:09 - 634:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:07)</b>	TP01.47
634:9	Q. So we're going to skip down	
634:10	to the part they omitted, which is	
634:11	Subparagraph 2, and I'd ask for you to	
634:12	read that into the record.	
634:14 - 635:01	<b>Prevoznik, Thomas 04-18-2019 (00:00:20)</b>	TP01.48

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	634:14 THE WITNESS: "The illegal 634:15 importation, manufacture, 634:16 distribution and possession and 634:17 improper use of controlled 634:18 substances have a substantial and 634:19 detrimental effect on the health 634:20 and general welfare of the 634:21 American people." 634:22 BY MR. FARRELL: 634:23 Q. Is this consistent with the 634:24 guidance provided by the DEA to 635:1 registrants?	
635:04 - 635:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.49
	635:4 THE WITNESS: Yes.	
636:22 - 637:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:39)</b> 636:22 Q. Go to the next slide. And 636:23 this is the United States Code Section, 636:24 which has a registration requirement. 637:1 And it includes a duty imposed upon the 637:2 registrants to comply with Paragraph 1. 637:3 Will you please read that into the 637:4 record? 637:5 A. "Maintenance of effective 637:6 control against diversion of particular 637:7 controlled substances into other than 637:8 legitimate medical, scientific, and 637:9 industrial channels." 637:10 Q. And is this consistent with 637:11 the guidance provided by the DEA to 637:12 registrants?	TP01.50
637:15 - 637:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.51
	637:15 THE WITNESS: Yes. Yes.	
638:10 - 638:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:28)</b> 638:10 Q. Title II, Control 638:11 Enforcement, states, "This bill provides 638:12 for control by the Justice Department of 638:13 problems related to drug abuse through 638:14 registration of manufacturers, 638:15 wholesalers, retailers, and all others in 638:16 the legitimate distribution chain, and	TP01.52

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
638:17	makes transactions outside the legitimate	
638:18	distribution chain illegal."	
638:19	Is this consistent with the	
638:20	guidance the DEA provided to registrants?	
638:24 - 638:24	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.53
638:24	THE WITNESS: Yes.	
639:02 - 639:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:20)</b>	TP01.54
639:2	Q. If you violate Section 823,	
639:3	or the provisions, the regulations	
639:4	enacted by the DEA related to the	
639:5	distribution of controlled substances,	
639:6	those acts are illegal. Agreed or	
639:7	disagree?	
639:10 - 639:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.55
639:10	THE WITNESS: Agreed.	
639:22 - 640:17	<b>Prevoznik, Thomas 04-18-2019 (00:00:42)</b>	TP01.56
639:22	Q. The quote from the	
639:23	congressional record is, "The bill is	
639:24	designed to improve the administration	
640:1	and regulation by the manufacturer" --	
640:2	"by the manufacturing, distribution and	
640:3	dispensing of controlled substances by	
640:4	providing a quote-unquote closed system	
640:5	of drug distribution for legitimate	
640:6	handlers of such drugs.	
640:7	"Such a closed system should	
640:8	significantly reduce the widespread	
640:9	diversion of these drugs out of	
640:10	legitimate channels into the illicit	
640:11	market, while at the same time providing	
640:12	the legitimate drug industry with a	
640:13	unified approach to narcotic and	
640:14	dangerous drug control."	
640:15	Is this consistent with the	
640:16	guidance provided by the DEA to	
640:17	registrants?	
640:20 - 640:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.57
640:20	THE WITNESS: Yes.	
641:14 - 641:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:13)</b>	TP01.58
641:14	Does the DEA take the	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
641:15 position that the purpose of the 641:16 Controlled Substances Act and its federal 641:17 regulations is to prevent diversion? 641:18 A. Yes.		
642:03 - 642:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b>	TP01.59
642:3 Q. Does the DEA agree that 642:4 diversion is foreseeable if registrants 642:5 fail to comply with federal law?		
642:10 - 642:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b>	TP01.60
642:10 THE WITNESS: Correct. 642:11 BY MR. FARRELL: 642:12 Q. And failure to comply 642:13 enables more diversion. Does the DEA 642:14 agree with that?		
643:01 - 643:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b>	TP01.61
643:1 THE WITNESS: Yes. 643:2 BY MR. FARRELL: 643:3 Q. Does the DEA believe that 643:4 more diversion is detrimental to public 643:5 health and safety?		
643:08 - 643:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:13)</b>	TP01.62
643:8 THE WITNESS: Yes. 643:9 BY MR. FARRELL: 643:10 Q. Does the DEA agree that the 643:11 more pills which unlawfully enter the 643:12 market results in more diversion?		
643:15 - 643:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.63
643:15 THE WITNESS: Yes.		
643:16 - 643:17	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.64
643:16 MR. FARRELL: Go to the next 643:17 slide.		
643:19 - 643:23	<b>Prevoznik, Thomas 04-18-2019 (00:00:11)</b>	TP01.65
643:19 Q. This is a provision about 643:20 penalties. Does the DEA agree that the 643:21 price for participation in illegal 643:22 traffic of controlled substances should 643:23 be prohibitive?		
644:11 - 644:11	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.66
644:11 THE WITNESS: Yes.		
644:11 - 644:16	<b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b>	TP01.67

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	644:11 THE WITNESS: Yes.	
	644:12 BY MR. FARRELL:	
	644:13 Q. Is this one of the reasons	
	644:14 that the DEA has escalated the amount of	
	644:15 fines that it has levied against	
	644:16 registrants that are repeated violators?	
644:22 - 644:22	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.68
	644:22 THE WITNESS: Yes.	
661:19 - 663:09	<b>Prevoznik, Thomas 04-18-2019 (00:01:52)</b>	TP01.69
	661:19 Q. All right. The next	
	661:20 document that I'm going to show you comes	
	661:21 from discovery in this case. And it's	
	661:22 the NWDA suspicious order monitoring	
	661:23 system.	
	661:24 And I believe that the	
	662:1 government has it included in its folder,	
	662:2 its materials file.	
	662:3 Have you seen this document	
	662:4 before?	
	662:5 A. Can I see more than that?	
	662:6 Q. I think it's under -- it's	
	662:7 in one --	
	662:8 A. In my tabs, my folder?	
	662:9 Q. Yeah.	
	662:10 A. Yes.	
	662:11 Q. I'll give you a second if	
	662:12 you want to flip through it.	
	662:13 A. That's all I see.	
	662:14 I'm familiar with this.	
	662:15 Q. This is a document that was	
	662:16 in the files of Cardinal Health. And	
	662:17 it's stamped as received in 1993, but	
	662:18 I'll represent to you that it contains	
	662:19 some older 1984 references later on.	
	662:20 I'm going just to ask you a	
	662:21 few basic questions about it. And I'll	
	662:22 represent to you that the NWDA is a trade	
	662:23 group for the wholesale distributors at	
	662:24 some point in time.	
	663:1 Go to Page 3.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	663:2 MR. FARRELL: Take that down 663:3 first if you don't mind. I'm 663:4 sorry. I was talking to John. 663:5 Take out the blowup. 663:6 Go ahead. Put it back up. 663:7 BY MR. FARRELL: 663:8 Q. So this is something very 663:9 specific that I want to ask the DEA.	
665:14 - 665:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:17)</b> 665:14 Q. Go all the way to Page 7. 665:15 In the middle of the page in Paragraph 9, 665:16 "Single suspicious orders." For purposes 665:17 of context I'd like you to read this 665:18 aloud.	TP01.70
665:21 - 666:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:28)</b> 665:21 THE WITNESS: "Single orders 665:22 of unusual size or deviation must 665:23 be reported immediately. The 665:24 submission of a monthly printout 666:1 of after-the-fact sales will not 666:2 relieve a registrant from the 666:3 responsibility of reporting these 666:4 single excessive or suspicious 666:5 orders. 666:6 "DEA has interpreted orders 666:7 to mean prior to shipment." 666:8 BY MR. FARRELL: 666:9 Q. Is this statement consistent 666:10 with the guidance provided by the DEA to 666:11 registrants? 666:12 A. Yes.	TP01.71
666:22 - 667:02	<b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b> 666:22 Q. I'm not asking you to 666:23 speculate. As a matter of fact, is this 666:24 consistent with what the DEA has told its 667:1 registrants is required to comply with 667:2 federal law?	TP01.72
667:10 - 667:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 667:10 THE WITNESS: Yes.	TP01.73
667:23 - 668:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	TP01.74

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
667:23	The next thing I'm going to	
667:24	do is I'm going to show you from Page 8,	
668:1	attached to this in the Cardinal Health	
668:2	files, is a cover sheet that says letters	
668:3	from DEA approving the format.	
668:4	And if you look, the first	
668:5	letter is dated April 27, 1984.	
668:6	Are you familiar with this	
668:7	correspondence?	
668:22 - 668:24	<b>Prevoznik, Thomas 04-18-2019 (00:00:03)</b>	TP01.75
668:22	Q. Are you familiar with this	
668:23	document?	
668:24	A. No.	
669:09 - 669:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:16)</b>	TP01.76
669:9	Q. Okay. So what I'm going to	
669:10	ask you is, is to flip to Page 2 and see	
669:11	Mr. Thomas Gitchell, acting chief	
669:12	diversion of operations section. Are you	
669:13	familiar with Mr. Gitchell?	
669:14	A. Yes, I know who he -- I know	
669:15	who he is.	
671:04 - 671:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b>	TP01.77
671:4	Q. The date is April 27, 1984.	
671:5	You'll see in the bottom right-hand	
671:6	corner this is a document that is in the	
671:7	Cardinal Health files.	
671:11 - 672:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:46)</b>	TP01.78
671:11	Q. And so I'm going to ask that	
671:12	the -- that the main paragraph be blown	
671:13	up so we can read it.	
671:14	So the NWDA policy that	
671:15	was -- that we just walked through, is	
671:16	what this reference is to.	
671:17	And I'd ask for you to read	
671:18	it, the portion that's highlighted.	
671:19	A. "The NWDA's draft format for	
671:20	a suspicious order" -- "order monitoring	
671:21	system provides an excellent framework	
671:22	for distributor registrants to design and	
671:23	operate a system to disclose to the	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
671:24	registrant suspicious orders of	
672:1	controlled substances."	
672:2	Q. Very good.	
672:3	Now I'd like you to read the	
672:4	next sentence.	
672:07 - 672:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	TP01.79
672:7	THE WITNESS: "However, I am	
672:8	compelled to note, as I have in	
672:9	our previous discussions, that any	
672:10	automated data processing system	
672:11	may provide the means and	
672:12	mechanism for compliance when the	
672:13	data is carefully reviewed and	
672:14	monitored by the wholesaler."	
672:15	BY MR. FARRELL:	
672:16	Q. Is this statement consistent	
672:17	with guidance provided by the DEA to	
672:18	registrants?	
673:02 - 673:16	<b>Prevoznik, Thomas 04-18-2019 (00:00:28)</b>	TP01.80
673:2	THE WITNESS: Yes.	
673:3	BY MR. FARRELL:	
673:4	Q. Now, go to the final	
673:5	sentence. Will you please read this	
673:6	aloud?	
673:7	A. "As previously discussed, an	
673:8	after-the-fact computer printout of sales	
673:9	data does not relieve a registrant of its	
673:10	responsibility to report excessive or	
673:11	suspicious orders when discovered. I am	
673:12	enclosing a copy of your draft with my	
673:13	pen and ink changes."	
673:14	Q. Is this consistent with the	
673:15	guidance provided by the DEA to	
673:16	registrants?	
673:19 - 673:19	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.81
673:19	THE WITNESS: Yes.	
674:08 - 674:13	<b>Prevoznik, Thomas 04-18-2019 (00:00:17)</b>	TP01.82
674:8	Q. Has after the fact reporting	
674:9	of suspicious orders ever been in	
674:10	compliance with federal law according to	



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
674:11 the DEA's guidance provided to 674:12 registrants? 674:13 A. No.		
675:03 - 675:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:16)</b>	TP01.83
675:3 Q. So from the Cardinal Health 675:4 files comes a second letter from the DEA. 675:5 And it's dated approximately three weeks 675:6 later, May 16, 1984. And it's again from 675:7 the DEA.		
679:18 - 680:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:26)</b>	TP01.84
679:18 Q. Would you please read the 679:19 highlighted section. 679:20 A. "However, I want to make it 679:21 clear that the submission of a monthly 679:22 printout of after-the-fact sales will not 679:23 relieve a registrant from the 679:24 responsibility of reporting excessive or 680:1 suspicious orders. DEA has interpreted 680:2 orders to mean prior to shipment." 680:3 Q. Is this statement consistent 680:4 with the guidance the DEA has always 680:5 provided to registrants?		
680:08 - 680:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.85
680:8 THE WITNESS: Yes.		
692:10 - 692:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:20)</b>	TP01.86
692:10 Q. Mr. Prevoznik, the next 692:11 document I'm going to reference is 692:12 actually in your notebook. 692:13 A. Okay. 692:14 Q. In the reliance materials 692:15 that you disclosed yesterday. 692:16 And it's the -- from the 692:17 1996 diversion investigators manual. 692:18 Section 5126.		
693:01 - 694:13	<b>Prevoznik, Thomas 04-18-2019 (00:01:32)</b>	TP01.87
693:1 Q. On behalf of the DEA, do you 693:2 recognize this document? 693:3 A. Yes, I do. 693:4 Q. What is it? 693:5 A. It is part of our diversion		

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693:6 investigators manual.  
 693:7 Q. What does that mean?  
 693:8 What -- what is a diversion  
 693:9 investigators manual?  
 693:10 A. It's a manual that breaks  
 693:11 down our responsibilities, our job.  
 693:12 It -- it covers the whole gambit of what  
 693:13 registration is -- what a registrant is,  
 693:14 down to record reports, requirements. It  
 693:15 goes through our scheduled  
 693:16 investigations, pre-registration  
 693:17 investigations, how to -- conducting  
 693:18 audits when we do the scheduled  
 693:19 investigation, what topics, what areas to  
 693:20 cover.  
 693:21 It covers controlled  
 693:22 substances -- controlled substances. It  
 693:23 also covers the chemicals, List I  
 693:24 chemicals, the requirements of that, as  
 694:1 well as preregistration investigations of  
 694:2 chemicals, applicants.  
 694:3 It covers the -- the gambit  
 694:4 of exactly what our job is.  
 694:5 Q. Are these -- in this page  
 694:6 that we're showing here, the bottom  
 694:7 right-hand corner is a Bates stamp. Can  
 694:8 you read that Bates stamp?  
 694:9 A. 00025231.  
 694:10 Q. Okay. Is this a document  
 694:11 produced by the DEA in this litigation at  
 694:12 the request of counsel for the diversion  
 694:13 investigators manual from 1996?  
 694:15 We'll stipulate that we  
 694:16 produced it.  
 694:17 MR. FARRELL: Thank you.  
 694:18 BY MR. FARRELL:  
 694:19 Q. So the title of Section 5126  
 694:20 says what?  
 694:21 A. Requirement to report

694:15 - 695:15

**Prevoznik, Thomas 04-18-2019 (00:00:46)**

TP01.88

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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694:22 suspicious orders.

694:23 Q. Would you read the first

694:24 sentence of the first paragraph aloud?

695:1 A. "Registrants are required to

695:2 inform DEA of suspicious orders in

695:3 accordance with 21 C.F.R. 1301.74(b).

695:4 DEA field offices are not to approve or

695:5 disapprove supplier shipments of

695:6 controlled substances. The

695:7 responsibility for making the decision to

695:8 ship rests with the supplier. No (sic)

695:9 exception to this occurs when a supplier

695:10 complies with a DEA field office's

695:11 request to initiate a controlled delivery

695:12 of controlled substances."

695:13 Q. Is this consistent with the

695:14 guidance provided by the DEA to

695:15 registrants?

695:17 - 696:10

**Prevoznik, Thomas 04-18-2019 (00:00:36)**

TP01.89

695:17 THE WITNESS: Yes.

695:18 MR. FARRELL: Now, if you'll

695:19 go down to -- keep going.

695:20 BY MR. FARRELL:

695:21 Q. Beginning with

695:22 "registrants," could you begin reading,

695:23 please.

695:24 A. "Registrants who routinely

696:1 report suspicious orders, yet fill these

696:2 orders, with reason to believe they are

696:3 destined for the illicit market, are

696:4 expressing an attitude of

696:5 irresponsibility that is detriment to the

696:6 public health and safety as set forth in

696:7 21 U.S.C. 823 and 824."

696:8 Q. Thank you. Is this

696:9 consistent with the guidance provided by

696:10 the DEA to registrants?

696:15 - 696:24

**Prevoznik, Thomas 04-18-2019 (00:00:23)**

TP01.90

696:15 THE WITNESS: Yes.

696:16 BY MR. FARRELL:

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	696:17 Q. So this is the official 696:18 policy of the DEA as of 1996, agreed? 696:19 A. Yes. 696:20 Q. Is this the position that 696:21 the DEA was instructing its diversion 696:22 investigators to take when looking into 696:23 cases involving the distribution of 696:24 controlled substances?	
697:06 - 697:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:12)</b>	TP01.91
	697:6 Q. In 1996. 697:7 A. Yes. 697:8 Q. Are you aware of any 697:9 deviation or change from that position by 697:10 the DEA since 1996?	
697:12 - 698:09	<b>Prevoznik, Thomas 04-18-2019 (00:00:43)</b>	TP01.92
	697:12 THE WITNESS: No. 697:13 BY MR. FARRELL: 697:14 Q. So the next sentence is just 697:15 a recitation of the suspicious order 697:16 definition. What I'd like you to do is 697:17 go down to where it starts, "The supplier 697:18 can determine," and begin reading aloud. 697:19 A. "The supplier can determine 697:20 whether the order is excessive by 697:21 checking their own sales and establishing 697:22 the average amount of controlled 697:23 substances shipped to registrants of the 697:24 same apparent size in a particular 698:1 geographic area." 698:2 Q. Read the next sentence, 698:3 please. 698:4 A. "If the customer exceeds 698:5 this threshold, the request should be 698:6 viewed as suspicious." 698:7 Q. Is this consistent with the 698:8 guidance that the DEA provided to 698:9 registrants since at least 1996?	
698:12 - 698:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.93
	698:12 THE WITNESS: Yes.	
700:04 - 700:09	<b>Prevoznik, Thomas 04-18-2019 (00:00:17)</b>	TP01.94

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
700:4 - 700:13	<p>700:4 Q. So if you take an average of</p> <p>700:5 the registrants in the area and you</p> <p>700:6 calculate that, if a customer exceeds</p> <p>700:7 that average, is that a red flag for a</p> <p>700:8 wholesale distributor that the order may</p> <p>700:9 be suspicious?</p> <p><b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b></p> <p>700:13 THE WITNESS: Yes.</p>	TP01.95
700:15 - 700:17	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b></p> <p>700:15 Q. And is that consistent with</p> <p>700:16 the directives the DEA has given to</p> <p>700:17 registrants since at least 1996?</p>	TP01.96
700:20 - 700:24	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b></p> <p>700:20 THE WITNESS: Yes.</p> <p>700:21 BY MR. FARRELL:</p> <p>700:22 Q. The next sentence, would you</p> <p>700:23 read, please.</p> <p>700:24 A. I forgot where I stopped.</p>	TP01.97
701:02 - 701:11	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:22)</b></p> <p>701:2 A. "This activity, over</p> <p>701:3 extended periods of time, would lead a</p> <p>701:4 reasonable person to believe that</p> <p>701:5 controlled substances possibly are being</p> <p>701:6 diverted.</p> <p>701:7 Q. Now, so what I'm asking you</p> <p>701:8 is, when you read this, is it fair to</p> <p>701:9 assume that this is consistent with the</p> <p>701:10 DEA's guidance to industry since at least</p> <p>701:11 1996?</p>	TP01.98
701:16 - 702:08	<p><b>Prevoznik, Thomas 04-18-2019 (00:00:38)</b></p> <p>701:16 THE WITNESS: Yes.</p> <p>701:17 BY MR. FARRELL:</p> <p>701:18 Q. Would you read the next</p> <p>701:19 sentence, please.</p> <p>701:20 A. "An investigation will be</p> <p>701:21 conducted for possible violation of the</p> <p>701:22 CSA and regulations upon determining that</p> <p>701:23 the reporting registrant, as a general</p> <p>701:24 practice, does not voluntarily halt</p> <p>702:1 shipments of controlled substances to</p>	TP01.99

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	702:2 registrants involved in suspected 702:3 diversion or to registrants against whom 702:4 previous action has been taken." 702:5 Q. Is this consistent with the 702:6 guidance provided by the DEA to 702:7 registrants since at least 1996? 702:8 A. Yes.	
702:24 - 703:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:26)</b> 702:24 Based upon this 1996 703:1 document, was it the DEA's position that 703:2 a registrant should halt shipments of 703:3 controlled substances that are involved 703:4 in suspected diversion? 703:5 A. Yes. 703:6 Q. And does that include when a 703:7 registrant has placed orders repeatedly 703:8 in excess of the regional average?	TP01.100
703:13 - 703:13	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 703:13 THE WITNESS: Yes.	TP01.101
709:02 - 709:06	<b>Prevoznik, Thomas 04-18-2019 (00:00:14)</b> 709:2 Q. Is it fair to reach the 709:3 conclusion that the DEA disclosed to 709:4 Cardinal Health in the year 2003 709:5 Section 5126 of the 1996 diversion 709:6 investigators manual?	TP01.102
709:10 - 709:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 709:10 THE WITNESS: Yes.	TP01.103
710:12 - 711:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:41)</b> 710:12 Q. Mr. Prevoznik, do you 710:13 recognize this document? 710:14 A. Yes. 710:15 Q. What is it? 710:16 A. It's a report to the U.S. 710:17 attorneys -- Attorney General. It's a 710:18 report by the suspicious orders task 710:19 force that was mandated to convene, and 710:20 it's their report based on the 710:21 Comprehensive Methamphetamine Control Act 710:22 in 1996. 710:23 Q. To the best of your	TP01.104

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	710:24 knowledge, is this a true and accurate 711:1 copy of the report provided by the United 711:2 States Drug Enforcement Administration to 711:3 Attorney General Janet Reno? 711:4 A. To the best of my knowledge, 711:5 yes. 711:6 Q. What is the date of the 711:7 document? 711:8 A. October 1998.	
712:07 - 712:17	<b>Prevoznik, Thomas 04-18-2019 (00:00:23)</b> 712:7 Q. Can you tell me in general, 712:8 do you -- does the DEA have an 712:9 understanding of what the purpose was of 712:10 this report that it generated for the 712:11 Attorney General? 712:12 A. It is our understanding that 712:13 this report was to discuss how to put a 712:14 suspicious ordering system forward to 712:15 handle the listed chemicals because of 712:16 the methamphetamine problem that we were 712:17 having in the United States.	TP01.105
712:18 - 713:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:32)</b> 712:18 Q. Now, this is also from the 712:19 executive summary. And it says that "the 712:20 charter required the establishment of a 712:21 task force to prepare recommendations 712:22 concerning additional guidelines to be 712:23 used by the chemical industry in 712:24 complying with 21 U.S.C. 830(b)(1)(A)." 713:1 Did I read that accurately? 713:2 A. Yes. 713:3 Q. Are you familiar with 713:4 21 U.S.C. 830(b)(1)(A)?	TP01.106
713:20 - 714:01	<b>Prevoznik, Thomas 04-18-2019 (00:00:24)</b> 713:20 This provision that we're 713:21 looking at, and the distinction that I 713:22 want to make, what is the DEA's 713:23 understanding of the types of 713:24 transactions that should be reported as 714:1 suspicious pursuant to 21 U.S.C. 830?	TP01.107

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
714:05 - 714:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:15)</b> 714:5 THE WITNESS: To regulate 714:6 a -- regulated transactions, a 714:7 transaction for -- in this 714:8 particular section, regarding 714:9 chemicals. 714:10 BY MR. FARRELL: 714:11 Q. So we are talking about 714:12 List I chemicals, not controlled 714:13 substances? 714:14 A. Correct.	TP01.108
715:04 - 715:11	<b>Prevoznik, Thomas 04-18-2019 (00:00:26)</b> 715:4 So under this report, it's 715:5 my understanding, is that the DEA was 715:6 complying with Section 21 U.S.C. 830, 715:7 which, if you read Paragraph 1(a) out 715:8 loud, requires what? Reports to the 715:9 Attorney General. It says, "Each 715:10 regulated person shall report to the 715:11 Attorney General." And what does A say?	TP01.109
715:14 - 716:03	<b>Prevoznik, Thomas 04-18-2019 (00:00:29)</b> 715:14 THE WITNESS: "Any regulated 715:15 transaction involving an 715:16 extraordinary quantity of a listed 715:17 chemical, an uncommon method of 715:18 payment or delivery, or any other 715:19 circumstance that the regulated 715:20 person believes may indicate that 715:21 the listed chemical will be used 715:22 in violation of this subchapter." 715:23 BY MR. FARRELL: 715:24 Q. So, I'm asking the DEA, the 716:1 Reno report from 1998, its authority 716:2 arises out of the Methamphetamine Act; is 716:3 that right?	TP01.110
716:09 - 716:09	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 716:9 THE WITNESS: Yes.	TP01.111
716:11 - 716:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:23)</b> 716:11 Q. And the definition of a 716:12 suspicious order under the	TP01.112



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	716:13 Methamphetamine Act is what? What size 716:14 transaction? 716:15 A. The extraordinary quantity. 716:16 Q. All right. Now, controlled 716:17 substances are not governed by the 716:18 methamphetamine act unless they contain 716:19 ephedrine or pseudoephedrine; is that 716:20 right?	
716:24 - 717:02	<b>Prevoznik, Thomas 04-18-2019 (00:00:03)</b> 716:24 Q. I'm asking you, the DEA? 717:1 A. Yeah. I'm waiting to make 717:2 sure --	TP01.113
717:06 - 717:06	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 717:6 THE WITNESS: Yes.	TP01.114
720:08 - 720:11	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b> 720:8 Q. Because it -- comparing a 720:9 List I chemical to a controlled 720:10 substance, is comparing apples to 720:11 oranges; is that fair?	TP01.115
720:14 - 720:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 720:14 THE WITNESS: Yes.	TP01.116
722:11 - 722:17	<b>Prevoznik, Thomas 04-18-2019 (00:00:22)</b> 722:11 Okay. So this was discussed 722:12 yesterday. I'm just trying to find 722:13 clarification. 722:14 This Reno report, according 722:15 to this note, applies to List I 722:16 chemicals, agreed? 722:17 A. Yes.	TP01.117
722:24 - 723:03	<b>Prevoznik, Thomas 04-18-2019 (00:00:15)</b> 722:24 Q. Second -- secondly, it can 723:1 apply to Control II and Control III 723:2 controlled substances that contain List I 723:3 chemicals. Agreed or disagree?	TP01.118
723:08 - 723:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 723:8 THE WITNESS: Agreed.	TP01.119
724:12 - 724:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:24)</b> 724:12 Q. We agree that this 724:13 document we're looking at from the Reno 724:14 report is guidance from the DEA to	TP01.120

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	724:15 registrants under the Methamphetamine Act 724:16 regarding looking for orders of 724:17 extraordinary size involving List I 724:18 chemicals. That's been established. And 724:19 I'm asking you whether or not you agree 724:20 with it.	
725:01 - 725:01	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.121
	725:1 THE WITNESS: Yes.	
734:19 - 735:06	<b>Prevoznik, Thomas 04-18-2019 (00:00:33)</b>	TP01.122
	734:19 Q. Will you continue reading? 734:20 A. "Cardinal Health understood 734:21 DEA to want orders for opioids reported 734:22 that exceeded a calculation endorsed by 734:23 DEA or that a wholesale distributor 734:24 otherwise identified as unusual in size, 735:1 pattern or frequency." 735:2 Q. Are you aware of the DEA 735:3 ever endorsing a calculation for opioids 735:4 to identify orders of unusual size, 735:5 pattern, or frequency? 735:6 A. No.	
737:12 - 737:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:25)</b>	TP01.123
	737:12 Q. So my question to the DEA, 737:13 is, did the DEA ever provide guidance to 737:14 Cardinal Health that it could use the 737:15 Reno report's definition of suspicious, 737:16 which is extraordinary size, as the 737:17 algorithm for measuring unusual orders of 737:18 controlled substances?	
737:22 - 737:23	<b>Prevoznik, Thomas 04-18-2019 (00:00:02)</b>	TP01.124
	737:22 THE WITNESS: Not to my 737:23 knowledge.	
738:14 - 738:23	<b>Prevoznik, Thomas 04-18-2019 (00:00:37)</b>	TP01.125
	738:14 Q. Cardinal Health is stating 738:15 in its discovery responses to the court 738:16 that the DEA provided guidance to them, 738:17 that they could use the Reno report and 738:18 its algorithm for orders of extraordinary 738:19 size to identify unusual orders of 738:20 controlled substances.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
738:21	Are you aware of the DEA	
738:22	providing such guidance to Cardinal	
738:23	Health?	
739:04 - 739:11	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	TP01.126
739:4	THE WITNESS: I am not	
739:5	aware.	
739:6	BY MR. FARRELL:	
739:7	Q. Is it the DEA's position	
739:8	that using an algorithm for extraordinary	
739:9	size is an appropriate measurement of	
739:10	orders of unusual size for controlled	
739:11	substances?	
739:17 - 739:24	<b>Prevoznik, Thomas 04-18-2019 (00:00:23)</b>	TP01.127
739:17	THE WITNESS: No.	
739:18	BY MR. FARRELL:	
739:19	Q. In fact, in the Reno report,	
739:20	the DEA provided recommendation and	
739:21	guidance to registrants that it could	
739:22	look for orders of extraordinary size of	
739:23	List I chemicals using a factor of three.	
739:24	Is that correct?	
740:05 - 740:05	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.128
740:5	THE WITNESS: Yes.	
747:09 - 747:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:22)</b>	TP01.129
747:9	Q. Has the DEA provided	
747:10	guidance to registrants of controlled	
747:11	substances that don't include List I	
747:12	chemicals that it can multiply the	
747:13	monthly average by three to identify	
747:14	orders that are merely unusual?	
747:19 - 747:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.130
747:19	THE WITNESS: Not to my	
747:20	knowledge.	
749:06 - 749:12	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	TP01.131
749:6	Has the DEA ever provided	
749:7	industrywide guidance that it could use	
749:8	the definition of suspicious order for	
749:9	the List I chemicals under the	
749:10	methamphetamine act for orders of	
749:11	controlled substances that do not include	

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749:13 - 749:13	749:12 List I chemicals? <b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.132
749:20 - 749:20	749:13 A. Not to my knowledge. <b>Prevoznik, Thomas 04-18-2019 (00:00:03)</b>	TP01.133
749:21 - 750:03	749:20 In the context of the first <b>Prevoznik, Thomas 04-18-2019 (00:00:30)</b>	TP01.134
750:07 - 750:08	749:21 sentence, has the DEA ever provided 749:22 guidance to registrants, which are, in 749:23 this case, distributors of Control II 749:24 prescription opioids, that it satisfies 750:1 its compliance obligations under federal 750:2 law by submitting after-the-fact 750:3 ingredient limit reports? <b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.135
750:10 - 750:13	750:7 THE WITNESS: Not to my 750:8 knowledge. <b>Prevoznik, Thomas 04-18-2019 (00:00:09)</b>	TP01.136
750:14 - 750:19	750:10 Q. Now, you'll recall from the 750:11 1996 diversion investigators manual, if 750:12 you'll flip back to it, which is 750:13 Exhibit 11. <b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b>	TP01.137
750:22 - 750:22	750:14 A. I'll use mine. The '96 one? 750:15 Q. The '96 one. 750:16 Is there any reference to 750:17 an -- an approved factor to be used by a 750:18 registrant to identify unusual orders of 750:19 controlled substances? <b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.138
752:06 - 752:09	750:22 THE WITNESS: No. <b>Prevoznik, Thomas 04-18-2019 (00:00:17)</b>	TP01.139
752:14 - 752:15	752:6 Q. Would the DEA ever endorse a 752:7 methodology for use by a registrant that 752:8 multiplied a monthly average by four to 752:9 determine orders of unusual size? <b>Prevoznik, Thomas 04-18-2019 (00:00:05)</b>	TP01.140
752:17 - 752:20	752:14 THE WITNESS: DEA doesn't 752:15 endorse the systems. <b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b>	TP01.141
	752:17 Q. Is using a factor of four	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
752:18 - 753:01	752:18 when calculating orders of unusual size 752:19 compliant with federal regulations 752:20 according to the DEA? <b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.142
752:24 - 753:01	752:24 THE WITNESS: Not to my 753:1 knowledge.	
755:02 - 755:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:07)</b> 755:2 Q. And is this a true and 755:3 accurate version of the 2004 chemical 755:4 handler's manual published by the DEA?	TP01.143
755:08 - 755:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 755:8 THE WITNESS: Yes.	TP01.144
755:09 - 755:15	<b>Prevoznik, Thomas 04-18-2019 (00:00:15)</b> 755:9 BY MR. FARRELL: 755:10 Q. Again, is this a document 755:11 that applies to List I chemicals, 755:12 including ephedrine and pseudoephedrine 755:13 and the chemicals used to make 755:14 methamphetamine? 755:15 A. Yes.	TP01.145
755:20 - 756:01	<b>Prevoznik, Thomas 04-18-2019 (00:00:17)</b> 755:20 Q. Does the DEA provide 755:21 guidance that this document is an 755:22 appropriate reference point for 755:23 monitoring suspicious orders of 755:24 controlled substances that do not include 756:1 List I chemicals?	TP01.146
756:06 - 756:06	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 756:6 THE WITNESS: No.	TP01.147
759:19 - 760:02	<b>Prevoznik, Thomas 04-18-2019 (00:00:25)</b> 759:19 Q. If a registrant that is a 759:20 wholesale distributor of controlled 759:21 substances, excluding those that contain 759:22 List I chemicals, is using E-3 to 759:23 identify suspicious orders of unusual 759:24 size, frequency or pattern, is that 760:1 compliant with federal law, according to 760:2 the DEA?	TP01.148
760:07 - 760:07	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 760:7 THE WITNESS: No.	TP01.149

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
761:01 - 761:14	<b>Prevoznik, Thomas 04-18-2019 (00:00:52)</b> 761:1 And tell me if you 761:2 recognize this document. 761:3 A. Yes. 761:4 Q. What is it? 761:5 A. It's a letter that DEA sent 761:6 to the distributors, registrants, by 761:7 Joe -- by Joe Rannazzisi who was the head 761:8 of the diversion program of DEA, it's 761:9 dated September 27th, 2006. 761:10 Q. Is this a true and accurate 761:11 copy of the letter sent by the DEA to all 761:12 registrants in the chain of distribution 761:13 of controlled substances? 761:14 A. Yes.	TP01.150
764:01 - 764:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:15)</b> 764:1 Q. So without belaboring the 764:2 point in going through this, is it the 764:3 DEA's position that anything in that 764:4 letter is a new rule?	TP01.151
764:08 - 764:08	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 764:8 THE WITNESS: No.	TP01.152
765:19 - 766:03	<b>Prevoznik, Thomas 04-18-2019 (00:00:21)</b> 765:19 Is this a true and accurate 765:20 copy of the second Rannazzisi letter sent 765:21 by the DEA to wholesale distributors of 765:22 prescription opioids dated December 27, 765:23 2007? 765:24 A. It went to manufacturers and 766:1 distributors. 766:2 Q. This one did? 766:3 A. Yes.	TP01.153
766:07 - 766:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:11)</b> 766:7 Q. Does the DEA believe that 766:8 there's anything in this letter that 766:9 constitutes a new rule? 766:10 A. No.	TP01.154
768:14 - 768:21	<b>Prevoznik, Thomas 04-18-2019 (00:00:10)</b> 768:14 (Video clip played as 768:15 follows:)	TP01.155

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
768:16 MR. FARRELL: During this 768:17 time frame prior to 2007, did 768:18 Cardinal report orders as 768:19 potentially suspicious or 768:20 suspicious orders, and then still 768:21 send the shipments out?		
768:24 - 769:04	<b>Prevoznik, Thomas 04-18-2019 (00:00:07)</b> 768:24 THE WITNESS: Yes, that is 769:1 the direction we received from the 769:2 DEA. We made the reports as 769:3 required and there was not a 769:4 shipping requirement.	TP01.156
770:06 - 770:11	<b>Prevoznik, Thomas 04-18-2019 (00:00:13)</b> 770:6 Cardinal Health claims that 770:7 it received direction from the DEA that 770:8 it could report suspicious orders and 770:9 then still ship it. 770:10 Is the DEA aware of 770:11 providing such guidance?	TP01.157
770:17 - 770:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:02)</b> 770:17 THE WITNESS: Not to my 770:18 knowledge.	TP01.158
771:07 - 771:10	<b>Prevoznik, Thomas 04-18-2019 (00:00:08)</b> 771:7 Q. Does the DEA take the 771:8 position that a registrant of controlled 771:9 substances has a duty to block shipments 771:10 of suspicious orders?	TP01.159
771:14 - 771:17	<b>Prevoznik, Thomas 04-18-2019 (00:00:06)</b> 771:14 THE WITNESS: Yes. 771:15 BY MR. FARRELL: 771:16 Q. Is that now and always been 771:17 the law in the United States of America?	TP01.160
771:20 - 771:20	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b> 771:20 THE WITNESS: Yes.	TP01.161
772:10 - 772:13	<b>Prevoznik, Thomas 04-18-2019 (00:00:06)</b> 772:10 Q. Okay. You saw the testimony 772:11 from Cardinal Health. 772:12 Do you believe the testimony 772:13 is accurate?	TP01.162
772:18 - 772:18	<b>Prevoznik, Thomas 04-18-2019 (00:00:01)</b>	TP01.163

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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807:02 - 807:19	<p>772:18 THE WITNESS: No.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:48)</b></p> <p>807:2 And again, building on the</p> <p>807:3 testimony from the previous two days without</p> <p>807:4 repeating it, I'm going to show you the</p> <p>807:5 bottom right-hand corner is US-DEA-00026146,</p> <p>807:6 and I'd ask you to read Roman Numeral IX into</p> <p>807:7 the record.</p> <p>807:8 A. "Single suspicious orders.</p> <p>807:9 Single orders of unusual size or deviation</p> <p>807:10 must be reported immediately. The submission</p> <p>807:11 of a monthly printout of after-the-fact sales</p> <p>807:12 will not relieve a registrant from the</p> <p>807:13 responsibility of reporting these single</p> <p>807:14 excessive or suspicious orders. DEA has</p> <p>807:15 interpreted 'orders' to mean prior to</p> <p>807:16 shipment."</p> <p>807:17 Q. So my question to you is, is</p> <p>807:18 this consistent with the guidance provided by</p> <p>807:19 the DEA to wholesalers and distributors?</p>	TP01.164
807:24 - 807:24	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b></p> <p>807:24 THE WITNESS: Yes.</p>	TP01.165
809:14 - 810:03	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b></p> <p>809:14 Q. Okay. And I've highlighted</p> <p>809:15 down -- a particular provision for emphasis</p> <p>809:16 to build on the previous two days' testimony.</p> <p>809:17 Beginning with "As previously discussed,"</p> <p>809:18 could you read that provision into the</p> <p>809:19 record?</p> <p>809:20 A. "An after-the-fact computer</p> <p>809:21 printout of sales data does not relieve a</p> <p>809:22 registrant of its responsibility to report</p> <p>809:23 excessive or suspicious orders when</p> <p>809:24 discovered."</p> <p>809:25 Q. Is this consistent with the</p> <p>810:1 guidance the DEA has provided to the</p> <p>810:2 wholesalers and manufacturers of prescription</p> <p>810:3 opioids?</p>	TP01.166
810:05 - 810:05	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>810:5 THE WITNESS: Yes.</p>	TP01.167



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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810:07 - 810:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b> 810:7 Q. I'm going to show you -- which 810:8 is the last page of this document. And 810:9 you'll see in the bottom right-hand corner is 810:10 US-DEA-00026150. It has the stamp of May 16, 810:11 1984.	TP01.168
810:16 - 810:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b> 810:16 A. It's a letter from Mr. Gitchel, 810:17 again, from DEA to the National Wholesales 810:18 Druggists' Association.	TP01.169
810:22 - 811:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:28)</b> 810:22 and I'd ask for you to read it 810:23 into the record. 810:24 A. "However, I want to make it 810:25 clear that the submission of a monthly 811:1 printout of after-the-fact sales will not 811:2 relieve a registrant from the responsibility 811:3 of reporting excessive or suspicious orders. 811:4 DEA has interpreted 'orders' to mean prior to 811:5 shipment." 811:6 Q. Is this consistent with the 811:7 guidance the DEA has provided to wholesalers 811:8 and manufacturers of prescription opioids?	TP01.170
811:11 - 811:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 811:11 THE WITNESS: Yes.	TP01.171
815:09 - 815:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:28)</b> 815:9 Q. If any distributor of 815:10 prescription opioids relies upon 815:11 after-the-fact sales reporting as the full 815:12 scope of its compliance with 1301.74(b), does 815:13 the DEA believe that it's sufficient to 815:14 satisfy the obligations under federal law?	TP01.172
815:18 - 815:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 815:18 THE WITNESS: No.	TP01.173
816:10 - 816:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:30)</b> 816:10 And I'll direct your attention 816:11 to the bottom right-hand corner with the 816:12 Bates stamp US-DEA-00026154. It has the 816:13 stamp of December 8, 1993, and I'm going to 816:14 ask you if you recognize this document.	TP01.174

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	816:15 A. Yes.	
	816:16 Q. What is this document?	
	816:17 A. This is an internal document	
	816:18 from Gene Haislip, our director of Office and	
	816:19 Diversion Control DEA, to the SAC, or special	
	816:20 agent in charge, of our Dallas field	
	816:21 division.	
820:07 - 820:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:47)</b>	TP01.175
	820:7 "Section 1301.74(b)," could you read the next	
	820:8 sentence?	
	820:9 A. "1301.74(b) of Title 21 of the	
	820:10 Code of Federal Regulations clearly places	
	820:11 the responsibility for designing and	
	820:12 operating a system to identify suspicious	
	820:13 orders of controlled substances on the	
	820:14 registrant. Implicit in this regulation is	
	820:15 the idea that the registrant should not	
	820:16 merely be accumulating data on what appear to	
	820:17 be excessive purchases for eventual	
	820:18 submission to DEA but rather that the system	
	820:19 be monitored so that any such orders will be	
	820:20 apparent to the registrant so that they -- so	
	820:21 that they can be reported to DEA upon	
	820:22 discovery and, whenever possible, before the	
	820:23 order is shipped."	
822:15 - 823:24	<b>Prevoznik, Thomas 05-17-2019 (00:01:44)</b>	TP01.176
	822:15 Q. Now, at the very bottom, there	
	822:16 is a discussion from the director beginning	
	822:17 with the last paragraph on the bottom of the	
	822:18 page beginning "what is -- what is of	
	822:19 particular concern."	
	822:20 Can you please read that into	
	822:21 the record?	
	822:22 A. "What is of particular concern	
	822:23 to me is the statement that appears on the	
	822:24 report submitted by the McKesson Corporation	
	822:25 in Fort Worth, Texas. For example, 'With the	
	823:1 submission of this report, we are leaving to	
	823:2 the DEA the final determination of whether	
	823:3 they are suspicious or unusual.' This	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	823:4 position is unacceptable and clearly in 823:5 contravention to the requirements of 21 CFR 823:6 1301.74(b). 823:7 "A registrant whose own 823:8 personnel are in the best position to 823:9 determine what is excessive or unusual based 823:10 on knowledge of their customers and usual 823:11 purchasing practices may not abrogate its 823:12 responsibility to identify suspicious orders 823:13 and to determine whether to ship or refuse to 823:14 ship the controlled substance order. 823:15 "The registrant must also 823:16 report any suspicious orders as soon as 823:17 possible to the DEA. This has been conveyed 823:18 to the McKesson national management in San 823:19 Francisco, and they have agreed to remove the 823:20 statement from reports." 823:21 Q. So on behalf of the DEA, can 823:22 you validate that this is a true and accurate 823:23 summary of the conversation between the DEA 823:24 and McKesson?	
824:02 - 824:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b> 824:2 THE WITNESS: Yes. 824:3 QUESTIONS BY MR. FARRELL: 824:4 Q. Is this consistent with the 824:5 guidance that DEA provided not only to 824:6 McKesson but to every other wholesale 824:7 distributor and manufacturer of prescription 824:8 opioids?	TP01.177
824:13 - 824:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 824:13 THE WITNESS: Yes.	TP01.178
834:21 - 834:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b> 834:21 So it should go 834:22 AmerisourceBergen first. The top 834:23 right is August 16, 2005, Bates stamp 834:24 US-DEA-00000147.	TP01.179
840:10 - 840:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 840:10 What I'd ask you to do is I'd 840:11 ask you to turn to page 7 of the PowerPoint 840:12 presentation with AmerisourceBergen.	TP01.180

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
840:23 - 841:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:56)</b> 840:23 Q. And if you look at the next 840:24 slide, it states, "Reporting a suspicious 840:25 order to the DEA does not relieve the 841:1 distributor of the responsibility to maintain 841:2 effective controls against diversion." 841:3 Did I read that accurately? 841:4 A. Yes. 841:5 Q. Okay. Why did the DEA put the 841:6 word "not" in all caps? 841:7 A. To emphasize that they had to 841:8 provide the suspicious order, not just -- not 841:9 just after-sales reports. 841:10 Q. The next slide, it says, "The 841:11 DEA cannot tell a distributor if an order is 841:12 legitimate or not" and that "the distributor 841:13 must determine which orders are suspicious 841:14 and make a sales decision." 841:15 Is this similar to all of the 841:16 other slide shows the DEA provided to the 841:17 distributors back in the 2000 -- 2005, 2006 841:18 time frame?	TP01.181
841:21 - 841:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 841:21 THE WITNESS: Yes.	TP01.182
841:23 - 842:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 841:23 Q. In other words, this PowerPoint 841:24 presentation, was it a stock PowerPoint 841:25 presentation that was shown to Cardinal 842:1 Health? 842:2 A. Yes. 842:3 Q. Was it shown to McKesson? 842:4 A. Yes.	TP01.183
842:18 - 842:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b> 842:18 Q. So I'm also going to have you 842:19 flip to page 12. 842:20 In the summary slides, the very 842:21 last bullet point, can you read what that 842:22 says? 842:23 A. "Not limited to Internet 842:24 pharmacies."	TP01.184

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
843:05 - 843:17	<p>842:25 Q. What does that mean?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b></p> <p>843:5 A. It's not just the -- what the</p> <p>843:6 Internet pharmacies was, but it would be any</p> <p>843:7 pharmacy, retail.</p> <p>843:8 Q. The very next slide, it says,</p> <p>843:9 "A pattern of drugs being distributed to</p> <p>843:10 pharmacies who are diverting controlled</p> <p>843:11 substances demonstrates the lack of effective</p> <p>843:12 controls against diversion by the</p> <p>843:13 distributor."</p> <p>843:14 This PowerPoint presentation in</p> <p>843:15 the distributor initiative meeting, it was</p> <p>843:16 not just limited to rogue Internet</p> <p>843:17 pharmacies, was it?</p>	TP01.185
843:20 - 843:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b></p> <p>843:20 THE WITNESS: No. The emphasis</p> <p>843:21 was regarding the Internet, but it was</p> <p>843:22 for the totality of their</p> <p>843:23 responsibilities as a registrant.</p>	TP01.186
845:18 - 846:04	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:33)</b></p> <p>845:18 Q. So the next plaintiff's exhibit</p> <p>845:19 has the Bates stamp at the bottom corner of</p> <p>845:20 US-DEA-00000371, and you'll see that it's</p> <p>845:21 dated January 23, 2006, but it's referencing</p> <p>845:22 a January 3, 2006 meeting.</p> <p>845:23 Do you see that?</p> <p>845:24 A. Yes.</p> <p>845:25 Q. And in it you can see where it</p> <p>846:1 looks like it contains -- this is the</p> <p>846:2 memorandum of the meeting between McKesson</p> <p>846:3 and the DEA as a result of the distributor</p> <p>846:4 initiative. Agreed?</p>	TP01.187
846:07 - 847:04	<p><b>Prevoznik, Thomas 05-17-2019 (00:01:06)</b></p> <p>846:7 THE WITNESS: Yes.</p> <p>846:8 QUESTIONS BY MR. FARRELL:</p> <p>846:9 Q. Now, what I'm going to ask you</p> <p>846:10 to do is I'm going to ask you to go to the</p> <p>846:11 end of page 2. And at the bottom, starting</p> <p>846:12 with the word "after," the very last</p>	TP01.188

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	846:13 paragraph, I'd ask you to read that into the 846:14 record. 846:15 A. "After the conclusion of this 846:16 meeting, it was learned from Gary Hilliard of 846:17 McKesson Corp that one of the reasons they 846:18 were not able to realize the full volume of 846:19 hydrocodone product going out to the Florida 846:20 pharmacies was that their reports only 846:21 included the name brand hydrocodone products 846:22 distributed and was leaving out the generic 846:23 products." 846:24 Q. The next sentence. 846:25 A. "It was only after realizing 847:1 that the generic were not being reported was 847:2 McKesson Corp then able to see the large 847:3 quantities that DEA was bringing to 847:4 McKesson's attention."	
847:17 - 847:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:20)</b> 847:17 Q. This document, following the 847:18 distributor initiative meeting between the 847:19 DEA and McKesson, appears to present the fact 847:20 that the DEA discovered McKesson was only 847:21 tracking brand name prescription opiates. 847:22 A. Correct.	TP01.189
848:03 - 848:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b> 848:3 Q. If, in fact, McKesson was only 848:4 tracking brand name prescription opiates and 848:5 leaving out the generic products, is that a 848:6 violation of federal law?	TP01.190
848:10 - 848:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b> 848:10 THE WITNESS: Yes.	TP01.191
849:12 - 849:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 849:12 Q. All right. On a scale of 0 of 849:13 10 of screw-ups, how big of a screw-up is 849:14 this?	TP01.192
849:22 - 850:01	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b> 849:22 THE WITNESS: In my personal 849:23 capacity, a big one, a really big one. 849:24 QUESTIONS BY MR. FARRELL: 849:25 Q. Epic?	TP01.193

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
850:18 - 851:09	<p>850:1 A. Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:01:10)</b></p> <p>850:18 Q. Now, without having to go</p> <p>850:19 through all of the nuances, what I'm going to</p> <p>850:20 ask you to do is I'm going to make a</p> <p>850:21 reference now. At the bottom right-hand</p> <p>850:22 corner is Bates stamp CAH_MDL2804_01376799.</p> <p>850:23 Do you see that? 799 are the</p> <p>850:24 last three numbers.</p> <p>850:25 A. Yes, I have it.</p> <p>851:1 Q. Now, in it, in this letter,</p> <p>851:2 Larry -- to Larry Cote from Cardinal Health's</p> <p>851:3 lawyers, it seems to indicate that controlled</p> <p>851:4 substances that are sold by Cardinal Health</p> <p>851:5 to CVS, Walgreens, Kroger, Kmart and Winn</p> <p>851:6 Dixie, which are large, national or regional</p> <p>851:7 chains, pose no threat of diversion due to</p> <p>851:8 their sophisticated anti-diversion systems</p> <p>851:9 and historical record of compliance.</p>	TP01.194
851:13 - 851:16	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b></p> <p>851:13 THE WITNESS: Yes.</p> <p>851:14 QUESTIONS BY MR. FARRELL:</p> <p>851:15 Q. Did I read that accurately?</p> <p>851:16 A. Yes.</p>	TP01.195
851:20 - 851:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b></p> <p>851:20 Q. Aside from me reading that</p> <p>851:21 accurately, is it true that large, national,</p> <p>851:22 regional chains of pharmacies pose no threat</p> <p>851:23 of diversion of prescription opioids?</p>	TP01.196
852:01 - 852:06	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b></p> <p>852:1 THE WITNESS: It's not true.</p> <p>852:2 QUESTIONS BY MR. FARRELL:</p> <p>852:3 Q. In fact, the DEA has</p> <p>852:4 investigated and prosecuted many of the large</p> <p>852:5 national or regional chains, including CVS</p> <p>852:6 and Walgreens?</p>	TP01.197
852:14 - 852:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>852:14 THE WITNESS: Yes.</p>	TP01.198
853:04 - 853:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b></p> <p>853:4 Q. Does the DEA consider -- if a</p>	TP01.199

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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853:19 - 853:20	<p>853:5 wholesale distributor came to the DEA and 853:6 said, "I've got a new customer and it's CVS, 853:7 which is a national chain store, and because 853:8 they have such swell security, I don't want 853:9 to monitor them for suspicious orders. Is 853:10 that okay?"</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>853:19 THE WITNESS: They can't do 853:20 that.</p>	TP01.200
854:19 - 854:25	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b></p> <p>854:19 Q. All right. Would the DEA 854:20 provide guidance to such a wholesale 854:21 distributor, that regardless of whether its 854:22 customer is a national chain pharmacy, the 854:23 distributor still must comply with 854:24 1301.74(b)? 854:25 A. Yes.</p>	TP01.201
863:05 - 863:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b></p> <p>863:5 So here you'll see the NWDA 863:6 suspicious order monitoring system, which we 863:7 were shown as Exhibit 18. 863:8 Is that familiar to you? 863:9 A. Yes. 863:10 Q. Okay. So in 1984 --</p>	TP01.202
863:16 - 863:19	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b></p> <p>863:16 MS. SINGER: I'm sorry. Oh, 863:17 I'm sorry, the new exhibit is 29. The 863:18 backup of the whole policy is 863:19 Exhibit 18.</p>	TP01.203
863:22 - 864:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:01:05)</b></p> <p>863:22 Q. Okay. And just directing your 863:23 attention very quickly to 2, sub 2, on your 863:24 monitor -- I'm sorry, 9 on your monitor, 863:25 single suspicious orders, is it correct that 864:1 this suspicious order monitoring system 864:2 publication from 1984 established that 864:3 "single orders of unusual size or deviation 864:4 must be reported immediately, the submission 864:5 of monthly printout of after-the-fact sales 864:6 will not relieve a registrant from the</p>	TP01.204



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	<p>864:7 responsibility of reporting these single</p> <p>864:8 excessive or suspicious orders. DEA has</p> <p>864:9 interpreted orders to mean prior to</p> <p>864:10 shipment"?</p> <p>864:11 Does that accurately reflect</p> <p>864:12 the policy of the DEA?</p> <p>864:13 A. Yes.</p> <p>864:14 Q. And that's as of 1984, correct?</p> <p>864:15 A. Correct.</p> <p>864:16 Q. All right. Turning next to</p> <p>864:17 1987 is our next marker in the timeline.</p> <p>864:18 And I'm sorry, just to be</p> <p>864:19 perfectly clear, from 1971 to the present,</p> <p>864:20 when the Controlled Substances Act was first</p> <p>864:21 enacted in '71, has it been the DEA's</p> <p>864:22 position that ILRs are not suspicious order</p> <p>864:23 reports?</p>	
864:25 - 865:05	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b></p> <p>864:25 THE WITNESS: Yes.</p> <p>865:1 QUESTIONS BY MS. SINGER:</p> <p>865:2 Q. And do ILRs relieve a</p> <p>865:3 registrant -- does submitting ILRs relieve a</p> <p>865:4 registrant of the obligation to report</p> <p>865:5 suspicious orders?</p>	TP01.205
865:07 - 866:01	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:49)</b></p> <p>865:7 THE WITNESS: No.</p> <p>865:8 QUESTIONS BY MS. SINGER:</p> <p>865:9 Q. All right. The next marker,</p> <p>865:10 1987, is that seminar report which was</p> <p>865:11 Prevoznik 17, and that established any system</p> <p>865:12 must be capable of both detecting individual</p> <p>865:13 orders or -- which are suspicious orders,</p> <p>865:14 which become suspicious over time due to</p> <p>865:15 frequency, quantity or pattern.</p> <p>865:16 Is that consistent with the</p> <p>865:17 DEA's policy?</p> <p>865:18 A. Yes.</p> <p>865:19 Q. And the DEA pointed out that</p> <p>865:20 the company is still responsible under their</p> <p>865:21 registrations for acting in the public</p>	TP01.206

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	865:22 interest, reporting the order does not in any 865:23 way relieve the firm from the responsibility 865:24 for the shipment. 865:25 Does that also reflect the 866:1 DEA's policy consistently over time?	
866:04 - 866:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.207
	866:4 THE WITNESS: Yes.	
868:17 - 870:21	<b>Prevoznik, Thomas 05-17-2019 (00:02:00)</b>	TP01.208
	868:17 Q. All right. I'd like to 868:18 turn your attention to Section 5126, which is 868:19 Bates number ending 301. 868:20 And I'm sorry, the Bates number 868:21 for this document is CAH_MDL_PRIOR 868:22 PRODUCTION_DEA07_01176247. 868:23 All right. So turning to 301, 868:24 which I think has been tabbed in your copy, 868:25 Mr. Prevoznik. 869:1 A. Yep. 869:2 Q. All right. Can you read the 869:3 third paragraph beginning "registrants"? 869:4 A. "Registrants who routinely 869:5 report suspicious orders, yet fill these 869:6 orders with reason to believe they are 869:7 destined for the illicit market, are 869:8 expressing an attitude of irresponsibility 869:9 that is a detriment to the public health and 869:10 safety as set forth in 21 USC 823 and 824." 869:11 Q. And 21 USC 823 and 824 the 869:12 Controlled Substances Act? 869:13 A. Yes. 869:14 Q. Okay. And does that statement 869:15 that you just read accurately reflect the 869:16 policy of the DEA in 1990? 869:17 A. Yes. 869:18 Q. And has that remained true 869:19 since then? 869:20 A. Yes. 869:21 Q. Okay. And then read from there 869:22 "suspicious orders"? 869:23 A. "Suspicious orders include	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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869:24 those which are in excess of legitimate  
 869:25 medical use or exhibit characteristics  
 870:1 leading to possible diversion, such as orders  
 870:2 of unusual size, unusual frequency, or those  
 870:3 deviating substantially from the -- from a  
 870:4 normal pattern."  
 870:5 Q. And keep going.  
 870:6 A. "The supplier can determine  
 870:7 whether the order is excessive by checking  
 870:8 their own sales and establishing the average  
 870:9 amount of controlled substances shipped to  
 870:10 registrants of the same apparent size in a  
 870:11 particular geographic area. If the customer  
 870:12 exceeds this threshold, the request should be  
 870:13 viewed as suspicious."  
 870:14 Q. One more sentence.  
 870:15 A. "This activity over extended  
 870:16 periods of time would lead a reasonable  
 870:17 person to believe that controlled substances  
 870:18 possibly are being diverted."  
 870:19 Q. And does the passage you just  
 870:20 read again reflect the DEA's policy?  
 870:21 A. Yes.

875:13 - 875:17 **Prevoznik, Thomas 05-17-2019 (00:00:14)**

TP01.209

875:13 Q. All right. So Exhibit 35 is  
 875:14 the NWDA Controlled Substances Manual, Bates  
 875:15 number HDA\_MDL\_000219360.  
 875:16 Mr. Prevoznik, have you seen  
 875:17 that document before?

875:18 - 875:18 **Prevoznik, Thomas 05-17-2019 (00:00:02)**

TP01.210

875:18 A. It looks familiar.

878:07 - 878:18 **Prevoznik, Thomas 05-17-2019 (00:00:21)**

TP01.211

878:7 Q. It says there, "Distributors  
 878:8 are responsible for designing and operating a  
 878:9 system that will disclose to the distributor  
 878:10 suspicious orders."  
 878:11 Do you agree that that is the  
 878:12 distributor's responsibility?  
 878:13 A. Yes.  
 878:14 Q. Okay. And then the note, "Many

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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878:15	distributors have been cited for failing to	
878:16	establish and maintain such a system."	
878:17	Is that also accurate?	
878:18	A. Yes.	
878:22 - 879:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:31)</b>	TP01.212
878:22	Q. Move to the next paragraph.	
878:23	"Distributor establishing suspicious order	
878:24	criteria. Distributors should establish	
878:25	written criteria of what constitutes a	
879:1	suspicious order. DEA leaves it to the	
879:2	distributor to make this determination. The	
879:3	key for the distributor is to establish	
879:4	reasonable criteria based upon customer	
879:5	purchasing patterns and then to adhere to	
879:6	them in monitoring orders."	
879:7	Does that several-step passage	
879:8	that I just read accurately reflect a	
879:9	distributor's duties under the CSA?	
879:13 - 879:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.213
879:13	THE WITNESS: Yes.	
879:15 - 879:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	TP01.214
879:15	Q. And do you see in this	
879:16	description of suspicious order criteria any	
879:17	expression of confusion or lack of clarity	
879:18	about what a suspicious order is?	
879:22 - 879:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.215
879:22	THE WITNESS: No.	
880:04 - 880:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:26)</b>	TP01.216
880:4	Q. Okay. So it says here,	
880:5	"Establish trigger levels, close quote, that	
880:6	only kick out purchasers buying substantially	
880:7	above the average for an item. The trigger	
880:8	level is established by multiplying the	
880:9	calculated average by an arbitrary factor.	
880:10	It is recommended that at the outset three	
880:11	times the average be used for ARCOS items and	
880:12	four times the average for non-ARCOS items."	
880:13	Do you see where I've just	
880:14	read?	
880:15	A. Yes.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
881:01 - 881:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 881:1 Q. Is it DEA's position that a 881:2 fixed multiplier of order levels is 881:3 sufficient as a system to identify suspicious 881:4 orders?	TP01.217
881:06 - 881:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b> 881:6 THE WITNESS: It could be one 881:7 criteria, but it can't be the only 881:8 one.	TP01.218
881:10 - 881:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b> 881:10 Q. Okay. And it says here, if you 881:11 keep reading on, "After the monitoring 881:12 program has been tested with live data and 881:13 the results analyzed, it may be necessary to 881:14 revise the factors." 881:15 Is it DEA's position that 881:16 distributors have an obligation to make sure 881:17 that any trigger or threshold they use 881:18 actually identifies suspicious orders?	TP01.219
881:23 - 881:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 881:23 THE WITNESS: Yes.	TP01.220
882:10 - 882:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b> 882:10 Q. Keep going. 882:11 A. "In these situations, DEA 882:12 should be notified before the order is 882:13 shipped, and a copy of all such orders should 882:14 be maintained in the distributor's suspicious 882:15 orders file, with a notation reflecting the 882:16 date and person contacted at DEA as well as 882:17 any guidance received."	TP01.221
882:18 - 882:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 882:18 Q. Go ahead and finish the 882:19 paragraph, please. 882:20 A. "The file also should indicate 882:21 whether the order was shipped. DEA usually 882:22 leaves the responsibility for determining 882:23 whether to ship to the distributor."	TP01.222
882:24 - 883:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b> 882:24 Q. And does this statement that 882:25 you just read from the NWDA manual of 1997	TP01.223

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
883:05 - 883:05	883:1 accurately describe the DEA's position on 883:2 what distributors should be -- or what 883:3 registrants should be doing? <b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.224
884:01 - 884:16	883:5 THE WITNESS: Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:30)</b> 884:1 Q. Okay. And there it -- the 884:2 first sentence reads, "DEA has not provided a 884:3 clear definition of what constitutes a 884:4 suspicious order." 884:5 Now that relates to a 884:6 suspicious order of List I chemicals, 884:7 correct? 884:8 A. Correct. 884:9 Q. Okay. And there NWDA is saying 884:10 we don't have a clear definition, correct? 884:11 A. Correct. 884:12 Q. And we didn't see that earlier 884:13 in the manual, correct? 884:14 A. Correct. 884:15 Q. All right. Then let's move to 884:16 Appendix M, which is one more page.	TP01.225
884:17 - 884:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b> 884:17 "What does DEA 884:18 consider to be a suspicious order?"	TP01.226
888:13 - 888:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b> 888:13 Q. And would DEA expect 888:14 that a registrant would remain -- excuse me, 888:15 would maintain copies of a suspicious order 888:16 reported to the DEA? 888:17 A. Yes.	TP01.227
889:22 - 890:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b> 889:22 QUESTIONS BY MS. SINGER: 889:23 Q. All right. Now, we think about 889:24 suspicious orders under CFR 1301.74, but the 889:25 registrant that ships suspicious orders also 890:1 fails to maintain effective controls to 890:2 prevent diversion; is that correct?	TP01.228
890:06 - 890:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 890:6 THE WITNESS: Correct.	TP01.229

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
890:23 - 891:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b> 890:23 Q. Would it make sense to the DEA 890:24 that a registrant could identify an order as 890:25 suspicious, report it to the DEA, not dispel 891:1 their suspicion, and then go ahead and ship 891:2 it so that it could be sold or used?	TP01.230
891:07 - 891:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b> 891:7 THE WITNESS: No, it would not 891:8 be correct.	TP01.231
891:10 - 891:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b> 891:10 Q. Why? 891:11 A. Because they're not maintaining 891:12 effective controls over diversion.	TP01.232
891:15 - 891:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b> 891:15 Q. And what happens if they go 891:16 ahead and just ship that suspicious order?	TP01.233
891:20 - 892:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:45)</b> 891:20 THE WITNESS: Well, it's -- 891:21 there was a -- there was a reason it 891:22 triggered the suspicion, so the 891:23 possibility or potential for it to be 891:24 diverted into the illicit market is 891:25 enhanced because it triggered a 892:1 suspicious order within their system. 892:2 So that being the underlying 892:3 cause for it to be triggered, that -- 892:4 the potential for it to be diverted, 892:5 now it's going -- the potential now is 892:6 greater that it's going into the 892:7 public and is going to affect the 892:8 public health and safety. 892:9 QUESTIONS BY MS. SINGER: 892:10 Q. Okay. And would going ahead 892:11 and shipping suspicious orders demonstrate an 892:12 attitude of irresponsibility, which I think 892:13 is the language of the Diversion 892:14 Investigators Manual, to the detriment of the 892:15 public health?	TP01.234
892:20 - 892:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 892:20 THE WITNESS: Yes.	TP01.235

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	892:21 QUESTIONS BY MS. SINGER:	
	892:22 Q. And has that always been true,	
	892:23 that shipping a suspicious order is a failure	
	892:24 of effective controls to prevent diversion?	
893:02 - 893:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.236
	893:2 THE WITNESS: Yes.	
893:12 - 893:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	TP01.237
	893:12 And, Mr. Prevoznik, can I	
	893:13 direct you -- and this is the deposition of	
	893:14 Tom Prevoznik, April 17, 2019.	
	893:15 All right. And if you could	
	893:16 turn to page 171. All right. And I want to	
893:17 - 893:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:16)</b>	TP01.238
	893:17 direct your attention to the middle of the	
	893:18 page where you testify: "It was a business	
	893:19 decision on whether to ship or not ship, that	
	893:20 we, DEA, were not going to direct a	
	893:21 registrant don't ship or not ship at that	
	893:22 time."	
894:03 - 894:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:23)</b>	TP01.239
	894:3 Q. Okay. And then if you turn the	
	894:4 page -- I'm sorry. At the bottom of	
	894:5 page 171, because -- so in 7, it was clear	
	894:6 that you were now directing registrants: Do	
	894:7 not ship.	
	894:8 And you said, right, because of	
	894:9 the Internet.	
	894:10 And then there's a question:	
	894:11 "And prior to December 2007, it was a	
	894:12 business decision by each registrant	
	894:13 recognizing what their own obligations were,	
	894:14 correct?"	
894:16 - 894:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.240
	894:16 THE WITNESS: Yes.	
894:20 - 894:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b>	TP01.241
	894:20 Q. And I just want to be clear.	
	894:21 Between -- before and after 2007, was it	
	894:22 always the policy of the DEA that registrants	
	894:23 could not ship suspicious orders?	
895:02 - 895:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.242



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
897:10 - 897:14	<p>895:2 THE WITNESS: Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b></p> <p>897:10 Q. Okay. And I want to make sure</p> <p>897:11 that your testimony is clear. When you say</p> <p>897:12 whether a suspicious order is subjective, do</p> <p>897:13 you mean that it varies from case to case, or</p> <p>897:14 it depends on who's looking at it?</p>	TP01.472
897:17 - 897:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b></p> <p>897:17 THE WITNESS: Both, really. It</p> <p>897:18 depends who's looking at it and</p> <p>897:19 what system do they have that's</p> <p>897:20 triggering the suspicious order. So</p> <p>897:21 it's whatever that registrant</p> <p>897:22 designed, which is specific to that</p> <p>897:23 registration.</p>	TP01.473
899:21 - 899:22	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b></p> <p>899:21 Q. Okay. Let's turn very quickly</p> <p>899:22 to the industry compliance guidelines.</p>	TP01.243
899:23 - 900:01	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b></p> <p>899:23 All right. I'm going to show</p> <p>899:24 you what's been marked as Exhibit 39.</p> <p>899:25 And this is Bates number</p> <p>900:1 CAH_MDL2804_00988458.</p>	TP01.244
900:05 - 900:09	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>900:5 Q. Okay. And do you recognize</p> <p>900:6 this to be the Healthcare Distribution</p> <p>900:7 Management Association's industry compliance</p> <p>900:8 guidelines?</p> <p>900:9 A. Yes.</p>	TP01.245
900:22 - 901:08	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:24)</b></p> <p>900:22 Q. Okay. And if you look at the</p> <p>900:23 first page, the third paragraph: "At the</p> <p>900:24 center of a sophisticated supply chain,</p> <p>900:25 distributors are uniquely situated to perform</p> <p>901:1 due diligence in order to help support the</p> <p>901:2 security of the controlled substances they</p> <p>901:3 deliver to their customers."</p> <p>901:4 Do you see what I've just read?</p> <p>901:5 A. Yes.</p> <p>901:6 Q. And does the DEA agree with</p>	TP01.246

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	901:7 that statement?	
	901:8 A. Yes.	
903:05 - 903:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:29)</b>	TP01.247
	903:5 Under the first paragraph,	
	903:6 Introduction: "Before opening an account" --	
	903:7 do you see where I am?	
	903:8 A. Yes.	
	903:9 Q. -- "the distributor should,	
	903:10 one, obtain background information on the	
	903:11 customer and the customer's business; review	
	903:12 that information carefully and, where	
	903:13 appropriate, verify that information; and	
	903:14 independently investigate the potential	
	903:15 customer."	
	903:16 Do you see what I've just read?	
	903:17 A. Yes.	
	903:18 Q. And does the DEA agree that	
	903:19 those are appropriate and necessary steps for	
	903:20 a registrant to take before shipping	
	903:21 controlled substances?	
903:23 - 903:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.248
	903:23 THE WITNESS: Yes.	
904:05 - 904:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.249
	904:5 Q. And that should cover the	
	904:6 average number of prescriptions filled each	
	904:7 day, average number of CS item prescriptions	
	904:8 filled each day.	
	904:9 Do you see where I am?	
	904:10 A. Yes.	
904:18 - 904:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.250
	904:18 Q. Okay. And then percentage of	
	904:19 controlled substances purchased compared to	
	904:20 overall purchases?	
	904:21 A. Yes.	
	904:22 Q. Would the DEA agree that those	
	904:23 are things that a registrant should be	
	904:24 looking at before shipping controlled	
	904:25 substances to a new customer?	
905:02 - 905:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b>	TP01.251
	905:2 THE WITNESS: Yes.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	905:3 QUESTIONS BY MS. SINGER:	
	905:4 Q. All right. And turning to the	
	905:5 next page, identify -- bottom bullet:	
	905:6 "Identification of physicians and other	
	905:7 treatment centers that are the potential	
	905:8 customer's most frequent prescribers or	
	905:9 highest purchasing doctors."	
	905:10 Do you see where I am?	
	905:11 A. Yes.	
	905:12 Q. And is that something that a	
	905:13 registrant should be doing as well?	
905:15 - 905:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.252
	905:15 THE WITNESS: Yes.	
906:11 - 906:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b>	TP01.253
	906:11 Q. And merely checking to see	
	906:12 whether a customer has a DEA registration,	
	906:13 would that be sufficient due diligence or	
	906:14 knowing your customer?	
906:17 - 907:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:31)</b>	TP01.254
	906:17 THE WITNESS: No.	
	906:18 QUESTIONS BY MS. SINGER:	
	906:19 Q. And it says here under	
	906:20 Additional Recommendations and Documentation,	
	906:21 the third bullet, "The performance and	
	906:22 results of all steps in the customer review	
	906:23 process should be fully documented as to each	
	906:24 potential customer, and such documentation	
	906:25 should be retained in an appropriate file."	
	907:1 Do you see what I've just read?	
	907:2 A. Yes.	
	907:3 Q. And does the DEA also agree	
	907:4 that that is an appropriate element, that	
	907:5 documenting due diligence or knowing your	
	907:6 customer is an appropriate element of that	
	907:7 program?	
907:10 - 907:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.255
	907:10 THE WITNESS: Yes.	
907:16 - 907:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b>	TP01.256
	907:16 Q. Okay. So it says here that	
	907:17 distributors -- I'm down at the second set of	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
907:18	bullets, the bottom bullet: "Thresholds for	
907:19	all new customer accounts should be	
907:20	established at the lowest level indicated by	
907:21	information obtained during the know your	
907:22	customer due diligence review."	
908:01 - 908:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.257
908:1	Q. And does the DEA agree that	
908:2	that is appropriate?	
908:05 - 908:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:26)</b>	TP01.258
908:5	THE WITNESS: I guess my	
908:6	concern would be that if you're --	
908:7	what is the lowest level? Is it what	
908:8	the customer is reporting what they	
908:9	said they ordered or is it -- you	
908:10	know, it could be like really a large	
908:11	amount, or is the registrant saying	
908:12	this is what we are going to say is	
908:13	the lowest amount.	
908:14	So I have a little trouble with	
908:15	that one.	
908:17 - 908:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b>	TP01.259
908:17	Q. Okay. So just making sure that	
908:18	we get this clear for the jury, the amount	
908:19	that a customer reports may be too high,	
908:20	correct?	
908:25 - 908:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.260
908:25	THE WITNESS: Yes.	
909:02 - 909:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	TP01.261
909:2	Q. And the registrant should be	
909:3	making its own judgment about what is not	
909:4	suspicious for a particular customer and not	
909:5	just accepting what they've previously	
909:6	ordered, correct?	
909:09 - 909:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b>	TP01.262
909:9	THE WITNESS: Correct.	
909:10	QUESTIONS BY MS. SINGER:	
909:11	Q. And they shouldn't be building	
909:12	in some excess above that level, correct?	
909:15 - 909:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.263
909:15	THE WITNESS: Yes.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
910:04 - 910:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b> 910:4 Q. And does the DEA agree that a 910:5 registrant should not just be looking at a 910:6 customer's controlled substances orders but 910:7 their controlled substance orders relative to 910:8 other products they're ordering?	TP01.264
910:11 - 910:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 910:11 THE WITNESS: Yes.	TP01.265
912:23 - 912:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 912:23 Q. And it -- again, that is the -- 912:24 that is what the Controlled Substances Act 912:25 requires, correct?	TP01.266
913:04 - 913:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 913:4 THE WITNESS: Correct.	TP01.267
913:13 - 913:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b> 913:13 Q. And does the DEA agree that a 913:14 registrant should have appropriately trained 913:15 and experienced compliance staff executing 913:16 its suspicious order monitoring and due 913:17 diligence process?	TP01.268
913:21 - 913:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 913:21 THE WITNESS: Yes.	TP01.269
913:23 - 914:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:31)</b> 913:23 Q. All right. Bates number 468, 913:24 subsection D, Documentation, it says under 913:25 that, "All investigations should be fully 914:1 documented, and all records of the 914:2 investigation should be retained in an 914:3 appropriate location within the firm, such as 914:4 with other records relating to the particular 914:5 customer." 914:6 Does the DEA agree with that 914:7 element of a compliant suspicious order 914:8 monitoring program?	TP01.270
914:11 - 914:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 914:11 THE WITNESS: Yes.	TP01.271
916:14 - 916:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b> 916:14 Q. Now, if an order is identified 916:15 as suspicious and not shipped but then held, 916:16 you know, not shipped, held until the next	TP01.272

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
916:24 - 916:24	<p>916:17 month when a threshold resets, is that order 916:18 still suspicious?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>916:24 THE WITNESS: Yes.</p>	TP01.273
917:02 - 917:03	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b></p> <p>917:2 Q. And should the registrant be 917:3 shipping that the next month?</p>	TP01.274
917:07 - 917:08	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b></p> <p>917:7 Q. Without first dispelling the 917:8 suspicion?</p>	TP01.275
917:12 - 917:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b></p> <p>917:12 THE WITNESS: Yes, they should 917:13 be relieving -- or ascertaining is 917:14 there suspicion or not.</p>	TP01.276
917:16 - 917:18	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b></p> <p>917:16 Q. And not shipping unless they 917:17 eliminate the basis for that suspicion? 917:18 A. Correct.</p>	TP01.277
917:23 - 918:22	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:56)</b></p> <p>917:23 Q. 469, sub F, Future Customer 917:24 Orders. "In instances where a distributor 917:25 concludes that an order is or remains 918:1 suspicious after conducting an investigation, 918:2 in addition to notifying DEA, it is 918:3 recommended that the distributor evaluate its 918:4 business relationship with the customer that 918:5 placed that order." 918:6 Do you see what I've just read? 918:7 A. Yes. 918:8 Q. "The distributor may consider 918:9 whether to subject future orders from that 918:10 same customer -- from that same customer for 918:11 the same drug code product or all controlled 918:12 substances to more rigorous scrutiny than was 918:13 applied before the determination that the 918:14 order is suspicious. The distributor may 918:15 also consider whether to cease filling all 918:16 future orders of that drug product code or 918:17 all controlled substances placed by that 918:18 customer."</p>	TP01.278

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
918:19 - 918:25	<p>918:19 Does the DEA agree that when a</p> <p>918:20 registrant identifies a suspicious order,</p> <p>918:21 they should also be looking more generally at</p> <p>918:22 that customer?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p>	TP01.279
918:25 - 919:02	<p>918:25 THE WITNESS: Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b></p>	TP01.280
919:02 - 919:07	<p>919:2 Q. And making a decision as to not</p> <p>919:3 only whether to fill that order but to</p> <p>919:4 continue filling orders for that customer?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p>	TP01.281
919:07 - 919:07	<p>919:7 THE WITNESS: Yes.</p>	
920:13 - 920:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b></p>	TP01.282
920:13 - 920:23	<p>920:13 Q. All right. Subsection B on</p> <p>920:14 Bates number 470, under Correspondence For</p> <p>920:15 Reporting, "It is recommended that all</p> <p>920:16 correspondence to DEA containing reports of</p> <p>920:17 suspicious orders should be sent registered</p> <p>920:18 mail with a return receipt requested, by</p> <p>920:19 electronic mail or by another system that</p> <p>920:20 creates for the distributor a permanent</p> <p>920:21 record that DEA has received the</p> <p>920:22 notification."</p>	
920:23 - 921:01	<p>920:23 Does the DEA agree with that?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:40)</b></p>	TP01.283
921:01 - 921:21	<p>921:1 THE WITNESS: Well, we have two</p> <p>921:2 different things going on. We have</p> <p>921:3 those that report to the field and</p> <p>921:4 those that have been under an action</p> <p>921:5 that is now dictated to go through</p> <p>921:6 electronically to headquarters.</p> <p>921:7 So, yes, if it's going to the</p> <p>921:8 office, that would be a great way to</p> <p>921:9 do it, to track that.</p> <p>921:10 QUESTIONS BY MS. SINGER:</p> <p>921:11 Q. Okay. And that C,</p> <p>921:12 Documentation, "All additional contact with</p> <p>921:13 DEA, either by telephone or in person, should</p> <p>921:14 be documented, and a record of the contact</p> <p>921:15 should be maintained."</p>	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	921:16 Does the DEA agree with that?	
	921:17 A. Yes.	
	921:18 Q. And is it fair to say that the	
	921:19 DEA would agree that a registrant should be	
	921:20 maintaining records of suspicious orders they	
	921:21 report to the DEA?	
921:25 - 922:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:30)</b>	TP01.284
	921:25 THE WITNESS: Yes.	
	922:1 QUESTIONS BY MS. SINGER:	
	922:2 Q. So while registrants, in going	
	922:3 through all of these different elements of	
	922:4 the industry compliance guidelines, which	
	922:5 we're now thankfully finished with, would the	
	922:6 DEA agree that whatever suspicious order	
	922:7 monitoring algorithm or system that a	
	922:8 registrant uses, that all of these elements	
	922:9 we just went through are elements of a	
	922:10 responsible and compliant program to prevent	
	922:11 diversion?	
922:14 - 922:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.285
	922:14 THE WITNESS: Yes.	
923:03 - 923:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b>	TP01.286
	923:3 Q. All right. Mr. Prevoznik,	
	923:4 Exhibit 40 is entitled "Draft DEA Comments	
	923:5 From the 6-04-08 Meeting on Suspicious	
	923:6 Orders." It's Bates number	
	923:7 CAH_MDL2804_03234535.	
924:14 - 924:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b>	TP01.287
	924:14 Q. Okay. Would the DEA agree that	
	924:15 in addition to completing a question --	
	924:16 having a potential customer complete a	
	924:17 questionnaire before a registrant agrees to	
	924:18 ship them a controlled substance, that a	
	924:19 registrant has to verify that the answers to	
	924:20 that questionnaire are accurate and complete?	
924:23 - 924:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.288
	924:23 THE WITNESS: Yes.	
926:03 - 926:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.289
	926:3 Do you agree with that first	
	926:4 underlined sentence, "DEA seemed to think the	



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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926:5	thresholds focus principally on volumes, and	
926:6	they express the view that an exclusive or	
926:7	even principal focus on volumes is	
926:8	inadequate"?	
926:9	A. Yes.	
927:12 - 928:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:36)</b>	TP01.290
927:12	Q. -- "DEA did not object to our	
927:13	recommendation that the particular drug or	
927:14	drugs that cause an order to be an order of	
927:15	interest or a suspicious order should not be	
927:16	shipped but other drugs can be. Their point	
927:17	was that in some circumstances the connection	
927:18	between that drug and another drug in the	
927:19	order should lead the wholesaler not to ship	
927:20	the other drug as well. Again, in their	
927:21	view, looking at a volume order drug by drug	
927:22	is not enough, and basing thresholds solely	
927:23	on volume is not enough. Even an order for a	
927:24	drug that does not meet a volume threshold	
927:25	may be suspicious in light of other aspects	
928:1	of the order."	
928:2	Does DEA agree with that	
928:3	statement?	
928:06 - 928:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.291
928:6	THE WITNESS: Yes.	
928:14 - 928:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.292
928:14	Q. "DEA was emphatic that if there	
928:15	were questions about an order, the order	
928:16	should not be shipped."	
928:17	Do you agree with that	
928:18	statement?	
928:21 - 928:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.293
928:21	THE WITNESS: Yes.	
929:13 - 929:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b>	TP01.294
929:13	Does the DEA agree that	
929:14	registrants should be reporting all	
929:15	suspicious orders, even orders that aren't	
929:16	shipped?	
929:20 - 930:01	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	TP01.295
929:20	THE WITNESS: Yes.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	929:21 QUESTIONS BY MS. SINGER:	
	929:22 Q. "Timeliness is very important.	
	929:23 DEA wants us to emphasize the need for rapid,	
	929:24 timely reporting."	
	929:25 Is that a point that DEA made	
	930:1 clear to registrants?	
930:06 - 930:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.296
	930:6 THE WITNESS: It's also	
	930:7 regulation upon discovery, so it's	
	930:8 immediately upon discovery.	
930:10 - 930:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.297
	930:10 Q. So that's a yes?	
	930:11 A. Yes.	
933:20 - 933:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b>	TP01.298
	933:20 Did the Rannazzisi letters, the	
	933:21 2006, 2007 letters, change the obligations of	
	933:22 registrants?	
	933:23 A. No.	
934:02 - 934:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.299
	934:2 Q. Did they reflect a new policy	
	934:3 or interpretation by DEA?	
934:06 - 934:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:40)</b>	TP01.300
	934:6 THE WITNESS: No, we were just	
	934:7 being more proactive to get the	
	934:8 registrants to see this was what was	
	934:9 going on. That's why we did the	
	934:10 distributor initiatives, to show them	
	934:11 with their own data, these are the	
	934:12 anomalies that we were seeing and	
	934:13 explaining to them this is what we	
	934:14 saw, and you should be paying	
	934:15 attention to these as well.	
	934:16 So the guidance letter -- or	
	934:17 not the guidance. The reiteration of	
	934:18 what their legal obligations were,	
	934:19 both statutorily and regulatory, were	
	934:20 in those letters, and it was to stop	
	934:21 what was going on at that time.	
	934:22 QUESTIONS BY MS. SINGER:	
	934:23 Q. And "stop" meaning the --	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
937:23 - 938:02	<p>934:24 A. The diversion of controlled 934:25 substances into the illicit market.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b></p> <p>937:23 Q. And do you think, does DEA 937:24 think, that the industry's failure to comply 937:25 with the Controlled Substances Act was due to 938:1 a failure to understand what the law required 938:2 of them?</p>	TP01.301
938:10 - 938:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>938:10 THE WITNESS: No.</p>	TP01.302
942:04 - 942:08	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b></p> <p>942:4 did the DEA, in the 942:5 Controlled Substances Act, make clear to 942:6 industry that the failure to prevent 942:7 diversion was a threat to public safety and 942:8 the public interest?</p>	TP01.303
942:13 - 943:06	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:41)</b></p> <p>942:13 part of the registrant that is 942:14 applying to be a registrant 942:15 understands that they have to maintain 942:16 effective controls. They have to 942:17 follow the state laws. They have to 942:18 not be convicted of, you know, 942:19 felonies or anything like that. 942:20 But also they also know that 942:21 these drugs themselves are scheduled 942:22 controlled substances for a particular 942:23 reason, because they're addictive, 942:24 psychologically and physically they're 942:25 addictive, so they know that these 943:1 drugs have these properties within 943:2 themselves. 943:3 So they would understand that 943:4 these drugs are categorized or 943:5 scheduled in that manner because they 943:6 have the potential to hurt.</p>	TP01.304
944:05 - 944:07	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b></p> <p>944:5 Q. Okay. So would the DEA let a 944:6 registrant know if it was aware of problems 944:7 with its suspicious order monitoring system?</p>	TP01.305

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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944:13 - 945:24	<p><b>Prevoznik, Thomas 05-17-2019 (00:01:16)</b></p> <p>944:13 THE WITNESS: So how I would  944:14 respond to this particular question is  944:15 when we sit down with a registrant and  944:16 they're explaining their system to us,  944:17 we are in a listening mode. We are  944:18 listening to what they say: "This is  944:19 what we're going to do. This is how  944:20 we're going to implement it. These  944:21 are the thresholds. These are the" --  944:22 whatever. They're explaining the  944:23 system to us, so we listen to what  944:24 they're saying.  944:25 If we, in listening to that,  945:1 they ask -- or we hear something that  945:2 doesn't sound quite right, we would  945:3 offer and say, "Well, you might want  945:4 to look at this."  945:5 Sort of exactly like the  945:6 Rannazzisi letters in which we laid  945:7 out the foundation of these are the  945:8 things that we're seeing. We're  945:9 having trouble trying to figure out  945:10 why this is going on. So we're asking  945:11 you to ask the same questions of  945:12 yourselves of the data that you're  945:13 seeing.  945:14 So what we're trying to do is  945:15 we're trying to put people in  945:16 compliance so that this stops, that  945:17 the diversion stops. So, yes, we  945:18 would -- we would offer suggestions to  945:19 them.  945:20 However, if we're into an  945:21 investigation or something where it --  945:22 where we are either investigating or  945:23 litigating, that might -- that  945:24 conversation might slow down.</p>	TP01.306
947:07 - 947:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>947:7 Q. Okay. So you testified, too,</p>	TP01.307

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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947:13 - 947:24	<p>947:8 that things can look good on paper or look 947:9 fine on paper, but what matters is how they 947:10 work in practice, correct?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:25)</b></p> <p>947:13 THE WITNESS: Well, the 947:14 regulations require two things: 947:15 design and operate. So the design 947:16 would be this is what we propose, this 947:17 is what our system looks like, and 947:18 then becomes, well, what, in fact, did 947:19 you do with the operation of it. 947:20 QUESTIONS BY MS. SINGER: 947:21 Q. Okay. And you, the DEA, can't 947:22 always see what distributors don't do or do 947:23 wrong, especially if they're trying not to be 947:24 caught, correct?</p>	TP01.308
948:04 - 948:04	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>948:4 THE WITNESS: Correct.</p>	TP01.309
948:08 - 948:13	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b></p> <p>948:8 Q. Okay. I want to turn to 948:9 Exhibit 42. 948:10 It is Exhibit Number 7 to the 948:11 Boggs deposition. It's called "American 948:12 Pain: The Largest US Pill Mill's Rise and 948:13 Fall."</p>	TP01.310
950:01 - 950:11	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b></p> <p>950:1 Q. Okay. So it says here, "Gary 950:2 Boggs, special agent with the DEA's Office of 950:3 Diversion Control, says the cases that the 950:4 DEA has brought in recent years involved 950:5 wholesalers knowingly making enormous sales 950:6 to customers that were per se in violation of 950:7 DEA's rules." 950:8 Do you see where I'm reading? 950:9 A. Yes. 950:10 Q. And does the DEA agree with 950:11 that statement?</p>	TP01.311
950:14 - 950:25	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b></p> <p>950:14 THE WITNESS: Yes. 950:15 QUESTIONS BY MS. SINGER:</p>	TP01.312

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	950:16 Q. And then it goes on quoting 950:17 Mr. Boggs, "The notion put out by HDMA that 950:18 somehow or another the DEA is not providing 950:19 essential information to them is simply not 950:20 accurate, says Boggs. It's a smokescreen. 950:21 It's a step out of desperation." 950:22 Do you see that statement? 950:23 A. Yes. 950:24 Q. Okay. Do you agree with that 950:25 statement?	
951:05 - 951:05	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.313
	951:5 THE WITNESS: Yes.	
951:18 - 951:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.314
	951:18 Q. All right. Exhibit 43, 951:19 Mr. Prevoznik. 951:20 This is MCKMDL00661483.	
951:24 - 952:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:55)</b>	TP01.315
	951:24 Q. All right. And this is an 951:25 e-mail Re: Report on House Energy and 952:1 Commerce Subcommittee Hearing on DEA and FDA 952:2 Transparency. 952:3 And I'll direct you to the 952:4 middle of the e-mail from Ann Berkey. 952:5 Do you see where I am? 952:6 A. Yes. 952:7 Q. Okay. And it's dated Tuesday, 952:8 April 8, 2014. 952:9 And if you look in the text of 952:10 that e-mail, it says, "I met today with Gary 952:11 Boggs, the new senior director of reg affairs 952:12 for US pharma for the east of the Mississippi 952:13 River, that is, who is based in Livonia. 952:14 He's a former top official with the DEA, and 952:15 we talked extensively about this bill, the 952:16 hearing, ways we can work with the Agency, et 952:17 cetera. He outlined in some detail the 952:18 processes that the DEA has had in place for 952:19 years to, quote, collaborate with wholesalers 952:20 in the way in which our industry, CAH" --	
953:17 - 953:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b>	TP01.316

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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953:17	Q. -- "has blown them off to the	
953:18	point that the DEA is now hammering all of	
953:19	us."	
953:20	Does this accurately reflect	
953:21	the sense of the -- is it true that the DEA	
953:22	felt that the industry did not respond to	
953:23	their guidance and request for compliance?	
954:07 - 954:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.317
	954:7 THE WITNESS: Yes.	
954:09 - 954:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b>	TP01.318
	954:9 Q. And this is as of 2014,	
	954:10 correct?	
954:14 - 954:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.319
	954:14 THE WITNESS: Yes, that's the	
	954:15 date on the e-mail.	
955:24 - 956:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:23)</b>	TP01.320
	955:24 Okay. Exhibit 44. This is	
	955:25 ABDCMDL00139028.	
	956:1 It's called Summary of DEA HDMA	
	956:2 meeting, December 19, 2011.	
	956:3 Do you recall a meeting between	
	956:4 the DEA and HDMA in 2011?	
956:07 - 956:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.321
	956:7 THE WITNESS: I don't.	
	956:8 QUESTIONS BY MS. SINGER:	
	956:9 Q. The DEA did meet with the HDMA	
	956:10 periodically, correct?	
956:13 - 957:01	<b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b>	TP01.322
	956:13 THE WITNESS: Correct.	
	956:14 QUESTIONS BY MS. SINGER:	
	956:15 Q. Okay. And down at the bottom	
	956:16 of the page here, in the last paragraph, it	
	956:17 says, "HDMA asked if there was any -- if	
	956:18 there were any noncompliance trends	
	956:19 throughout the wholesale distribution	
	956:20 industry we should inform our members about."	
	956:21 Do you see where I am?	
	956:22 A. Yes.	
	956:23 Q. Okay. "Gary Boggs" --	
	956:24 Who we talked about just a	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	956:25 minute ago, correct?	
	957:1 A. Yes.	
957:04 - 957:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:46)</b>	TP01.323
	957:4 Q. -- "the executive assistant to	
	957:5 the deputy administrator for diversion	
	957:6 control, led this response. He stated that	
	957:7 DEA's single greatest concern was their	
	957:8 belief that wholesaler distributors were lax	
	957:9 in analysis, review and acting on their own	
	957:10 ARCOS data. He stated that sometimes the	
	957:11 data were pretty egregious. He went on to	
	957:12 explain," turning the page, "that the Agency	
	957:13 had not seen changes in registrants' behavior	
	957:14 that it expected after presenting its	
	957:15 analysis of ARCOS data to them, so we have --	
	957:16 quote, 'so we have upped our game.'"	
	957:17 Is this consistent with the	
	957:18 DEA's view and your testimony that	
	957:19 registrants were lax in their analysis,	
	957:20 review and acting on their own ARCOS data?	
957:23 - 957:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.324
	957:23 THE WITNESS: Yes.	
957:25 - 957:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	TP01.325
	957:25 Q. And was it pretty egregious?	
958:04 - 958:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.326
	958:4 THE WITNESS: Yes.	
958:06 - 958:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.327
	958:6 Q. And when it says here that DEA	
	958:7 had "upped its game," do you know what that's	
	958:8 referring to?	
958:12 - 958:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.328
	958:12 THE WITNESS: At this time	
	958:13 period, we were investigating and	
	958:14 litigating against the wholesalers.	
	958:15 QUESTIONS BY MS. SINGER:	
	958:16 Q. Okay. Prompted by DEA's sense	
	958:17 that that's what they needed to do given a	
	958:18 lack of voluntarily compliance, correct?	
958:22 - 958:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.329
	958:22 THE WITNESS: Yes.	



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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962:04 - 962:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b> 962:4 Q. All right. In your testimony 962:5 on day one or day two, you were asked whether 962:6 suspicious orders always lead to diversion. 962:7 Do you remember? 962:8 A. Yes.	TP01.330
962:12 - 962:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b> 962:12 Q. Okay. And I think your answer 962:13 to that was, no, it doesn't always lead to 962:14 diversion. 962:15 Does that seem right to you?	TP01.331
962:18 - 962:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 962:18 THE WITNESS: Yes.	TP01.332
962:20 - 962:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b> 962:20 Q. Okay. And is that because, 962:21 Mr. Prevoznik, not all suspicious orders turn 962:22 out to actually be suspicious? 962:23 A. Correct.	TP01.333
963:02 - 963:05	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b> 963:2 Q. Okay. But if a distributor 963:3 doesn't investigate a suspicious order, it 963:4 wouldn't know whether that order was being 963:5 diverted, right?	TP01.334
963:08 - 963:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 963:8 THE WITNESS: Yes.	TP01.335
963:10 - 963:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:17)</b> 963:10 Q. And to use the language we 963:11 quoted earlier from the Diversion 963:12 Investigators Manual, sending out potentially 963:13 suspicious orders without investigating them 963:14 reflects a, quote, attitude of 963:15 irresponsibility. 963:16 Does DEA agree?	TP01.336
963:19 - 963:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 963:19 THE WITNESS: Yes.	TP01.337
963:23 - 964:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:50)</b> 963:23 Q. Let's turn to the Energy and 963:24 Commerce. Since we don't have previous -- 963:25 the exhibits from last time, we're going to 964:1 remark the Energy and Commerce report as	TP01.338

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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964:2 Exhibit 46. It's the same report that went  
 964:3 in earlier in your testimony.  
 964:4 And industry lawyers asked  
 964:5 you -- they showed you a piece of the report  
 964:6 that said that DEA could have acted earlier.  
 964:7 Do you remember those  
 964:8 questions?  
 964:9 A. Vaguely, but, yes.  
 964:10 Q. Okay. And certainly this  
 964:11 Energy and Commerce report finds the DEA  
 964:12 could have done more than it did, correct?  
 964:13 A. Correct.  
 964:14 Q. Okay. But it's also highly  
 964:15 critical of distributors, is it not?

964:21 - 964:24

**Prevoznik, Thomas 05-17-2019 (00:00:06)**

TP01.339

964:21 THE WITNESS: Yes.  
 964:22 QUESTIONS BY MS. SINGER:  
 964:23 Q. Okay. And just for context, I  
 964:24 want to direct you to page 5 of the report.

964:25 - 965:24

**Prevoznik, Thomas 05-17-2019 (00:01:02)**

TP01.340

964:25 On the bottom of the page, it  
 965:1 says in that last paragraph, "As the opioid  
 965:2 epidemic began to surge, the DEA, by 2005,  
 965:3 realized that traditional policing of  
 965:4 individual doctors and pharmacies was no  
 965:5 longer an effective approach against the  
 965:6 oncoming avalanche of opioids from rogue  
 965:7 Internet pharmacies and pill mills. Instead,  
 965:8 DEA's focus turned to the drug wholesale  
 965:9 distributors, a choke point in the  
 965:10 pharmaceutical supply chain, who transfer  
 965:11 drugs from manufacturers to businesses such  
 965:12 as clinics, hospitals and pharmacies where  
 965:13 they can be dispensed to patients.  
 965:14 Distributors in previous years had not  
 965:15 received enforcement attention from the DEA.  
 965:16 The new focus looked for greater impact for  
 965:17 the highly consolidated industry given the  
 965:18 three -- given that the three major drug  
 965:19 distributors - AmerisourceBergen, Cardinal

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	965:20 Health and McKesson - control about 965:21 85 percent of the drug supply." 965:22 Do you agree with the statement 965:23 I've just read? 965:24 A. Yes.	
966:02 - 966:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:50)</b> 966:2 Q. And then "Beginning in 2005, 966:3 the DEA undertook a series of initiatives 966:4 meant to educate wholesale drug distributors 966:5 about their legal obligations to prevent 966:6 controlled substance diversion. The DEA's 966:7 distributor initiative included one-on-one 966:8 meetings with wholesale distributors in which 966:9 DEA officials provided specific examples 966:10 regarding distributors' own customers whose 966:11 ordering habits were suggestive of trends 966:12 indicating the presence of diversion and 966:13 illicit Internet pharmacies. Of the five 966:14 distributors investigated by the committee, 966:15 AmerisourceBergen, Cardinal, HD Smith and 966:16 McKesson, each had one-on-one meetings with 966:17 DEA as part of this initiative. In addition, 966:18 during 2006 and 2007, the DEA sent a series 966:19 of three letters, sent to all DEA-registered 966:20 distributors outlining their legal 966:21 obligations to conduct due diligence and 966:22 report suspicious orders." 966:23 Is that also an accurate 966:24 statement of what happened?	TP01.341
967:02 - 967:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 967:2 THE WITNESS: Yes.	TP01.342
967:04 - 967:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:20)</b> 967:4 Q. "Apparently the DEA soon 967:5 realized that the largest distributors were 967:6 not taking their compliance requirements with 967:7 sufficient seriousness. In 2007 and 2008, 967:8 the DEA took enforcement action through legal 967:9 settlements against the three largest 967:10 wholesale distributors in the US for alleged 967:11 violations of the CSA, with multi-million	TP01.343

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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967:12	dollar fines involving two of them."	
967:13	Is that also accurate?	
967:17 - 968:19	<b>Prevoznik, Thomas 05-17-2019 (00:01:16)</b>	TP01.344
967:17	THE WITNESS: Yes.	
967:18	QUESTIONS BY MS. SINGER:	
967:19	Q. Last paragraph. "Despite these	
967:20	settlement agreements and the subsequent	
967:21	policy enhancements that the three	
967:22	distributors made in their aftermath, the	
967:23	committee found that the distributors	
967:24	continued to ship large volumes of opioids	
967:25	into West Virginia. The three largest	
968:1	wholesale drug distributors in the United	
968:2	States - AmerisourceBergen, Cardinal Health	
968:3	and McKesson - sent more than 900 million	
968:4	doses of hydrocodone and oxycodone to West	
968:5	Virginia between 2005 and 2016. Cardinal	
968:6	Health was the largest supplier of controlled	
968:7	substances to West Virginia out of the five	
968:8	companies examined as part of the Committee's	
968:9	investigation, and distributed more than 366	
968:10	million doses of hydrocodone and oxycodone to	
968:11	West Virginia pharmacies between 2005 and	
968:12	2016. From April 2006 through 2016, McKesson	
968:13	supplied 299.87 million doses of hydrocodone	
968:14	and oxycodone to West Virginia pharmacies,	
968:15	AmerisourceBergen distributed 248.16 million	
968:16	doses of hydrocodone and oxycodone to West	
968:17	Virginia pharmacies between 2005 and 2016."	
968:18	Is that also consistent with	
968:19	DEA's understanding of what had occurred?	
968:22 - 968:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.345
968:22	THE WITNESS: Yes.	
968:24 - 969:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:25)</b>	TP01.346
968:24	Q. Turn the page, please. "Among	
968:25	the Committee's findings, distributors	
969:1	suffered a series of breakdowns or had a lack	
969:2	of follow-through in their -- through in	
969:3	their due diligence evaluations of	
969:4	prospective pharmacy customers. As	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	969:5 demonstrated in the report, the committee 969:6 found instances of insufficient due diligence 969:7 by distributors who merely required 969:8 pharmacies to complete new customer 969:9 applications." 969:10 Now, we talked about that 969:11 earlier, correct?	
969:14 - 969:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 969:14 THE WITNESS: Correct. 969:15 QUESTIONS BY MS. SINGER: 969:16 Q. And that is not sufficient to 969:17 comply with the registrant's obligation to 969:18 know their customers, correct?	TP01.347
969:23 - 969:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 969:23 THE WITNESS: Correct.	TP01.348
969:25 - 970:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:18)</b> 969:25 Q. "There were cases where data 970:1 submitted by a new customer was not 970:2 critically analyzed to identify any red flags 970:3 of controlled substance diversion, for 970:4 example, potential red flags regarding a 970:5 pharmacy's prescribing physicians that raised 970:6 concerns about possible diversion were not 970:7 questioned." 970:8 Is that consistent with DEA's 970:9 understanding of what occurred?	TP01.349
970:12 - 970:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 970:12 THE WITNESS: Yes.	TP01.350
970:14 - 971:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:42)</b> 970:14 Q. Goes on to say, "The 970:15 investigation found instances where there 970:16 were failures to monitor the volume of 970:17 controlled substances sold to customers. 970:18 Some distributors used thresholds to track 970:19 customers' purchases of controlled substances 970:20 and flag orders as suspicious when purchases 970:21 exceeded those limits. But some of these 970:22 thresholds were assigned arbitrarily and not 970:23 effective. Committee found instances in 970:24 which distributors set thresholds but failed	TP01.351

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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	970:25 to enforce them, assigned artificially high 971:1 hydrocodone threshold limits with little to 971:2 no documented justification, or continued to 971:3 raise threshold levels without thoroughly 971:4 investigating or documenting the 971:5 justifications presented by a customer 971:6 pharmacy." 971:7 Again, is that what DEA 971:8 observed happened during this time period?	
971:13 - 971:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.352
	971:13 THE WITNESS: Yes.	
972:04 - 973:05	<b>Prevoznik, Thomas 05-17-2019 (00:00:58)</b>	TP01.353
	972:4 Q. It goes on, "Despite efforts by 972:5 DEA to educate distributors about their 972:6 responsibility to report suspicious orders, 972:7 the companies reviewed by the committee 972:8 failed to address suspicious orders" -- I'm 972:9 sorry -- "suspicious order monitoring in 972:10 critical ways. Rather than reporting 972:11 individual suspicious orders as they were 972:12 identified, some distributors reported a 972:13 variety of other types of information to DEA 972:14 over the years. This information included 972:15 excessive orders encompassing drug shipments 972:16 that had already been shipped and suspicious 972:17 customers such as pharmacies with which 972:18 distributors had terminated business 972:19 relationships. Neither of these types of 972:20 reports informed DEA about suspicious orders 972:21 in realtime, nor did they guarantee the 972:22 suspicious orders reported to DEA were also 972:23 blocked by the distributors. The committee 972:24 also found that one distributor lacked any 972:25 formal order monitoring program. Rather, the 973:1 distributor's employees relied on subjective 973:2 criteria to investigate [sic] orders it 973:3 considered suspicious." 973:4 Does that also reflect what the 973:5 DEA knew to happen during this time period?	
973:10 - 974:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:56)</b>	TP01.354

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973:10 THE WITNESS: Yes.

973:11 QUESTIONS BY MS. SINGER:

973:12 Q. And the last paragraph.

973:13 "Another critical failure identified by the

973:14 Committee involved instances in which

973:15 distributors appeared to turn a blind eye to

973:16 red flags of possible drug diversion.

973:17 Despite available information, distributors

973:18 at times took only minimal steps to

973:19 investigate possible warning signs of

973:20 diversion and continued to ship controlled

973:21 substances to suspect pharmacies. In several

973:22 cases, distributors either failed to fully

973:23 investigate potentially troubling information

973:24 they obtained from customer pharmacies or

973:25 willfully ignored it. These failures raise

974:1 substantial concern given that DEA has said

974:2 existing knowledge of a geographic area's

974:3 problem with controlled substance abuse is a

974:4 factor that distributors should take into

974:5 account when evaluating customers."

974:6 Now, is that true, that DEA had

974:7 said knowledge of a geographic area's problem

974:8 with controlled substance abuse is a factor

974:9 that should be taken into account by

974:10 registrants?

974:14 - 974:25

**Prevoznik, Thomas 05-17-2019 (00:00:22)**

TP01.355

974:14 THE WITNESS: Yes.

974:15 QUESTIONS BY MS. SINGER:

974:16 Q. Okay. "West Virginia has the

974:17 highest drug overdose rate in the country,

974:18 meaning distributors should have been

974:19 particularly attuned to any red flags

974:20 encountered when conducting due diligence on

974:21 pharmacies in that state."

974:22 Is that also an accurate

974:23 reflection of a registrant's duty when

974:24 shipping controlled substances into West

974:25 Virginia or other hotspots?

975:05 - 975:10

**Prevoznik, Thomas 05-17-2019 (00:00:09)**

TP01.356

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	975:5 THE WITNESS: Yes.	
	975:6 QUESTIONS BY MS. SINGER:	
	975:7 Q. Okay. And this whole paragraph	
	975:8 that I just read, does that also reflect the	
	975:9 DEA's understanding of what happened during	
	975:10 this time period?	
975:16 - 975:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.357
	975:16 THE WITNESS: Yes.	
978:16 - 979:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:38)</b>	TP01.358
	978:16 Q. Okay. Turning towards the	
	978:17 middle of the page, just below it, the second	
	978:18 paragraph from the bottom. "But as	
	978:19 demonstrated by the Committee's	
	978:20 investigation, the DEA did not always receive	
	978:21 the level of compliance required under the	
	978:22 CSA. The five distributors whose actions in	
	978:23 West Virginia were examined by the Committee	
	978:24 each had unique failures. The companies had	
	978:25 various policies and procedures in place to	
	979:1 prevent diversion but in some cases did not	
	979:2 adequately follow or carry out those	
	979:3 policies. As evidenced in the case studies	
	979:4 discussed in each section, distributors had	
	979:5 failings on multiple fronts."	
	979:6 Is that consistent with the	
	979:7 DEA's conclusions?	
979:12 - 979:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:26)</b>	TP01.359
	979:12 THE WITNESS: Yes.	
	979:13 QUESTIONS BY MS. SINGER:	
	979:14 Q. "For instance, it is not	
	979:15 sufficient due diligence for a distributor to	
	979:16 only require prospective or existing	
	979:17 customers to complete pharmacy questionnaires	
	979:18 or supply supplemental data. The information	
	979:19 disclosed on such questionnaires or the data	
	979:20 submitted must also be critically analyzed to	
	979:21 identify any red flags of controlled	
	979:22 substance diversion."	
	979:23 Does that accurately reflect a	
	979:24 distributor's obligations or a registrant's	



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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980:03 - 980:10	<p>979:25 obligations?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b></p> <p>980:3 THE WITNESS: Yes.</p> <p>980:4 QUESTIONS BY MS. SINGER:</p> <p>980:5 Q. "Once distributors bring</p> <p>980:6 pharmacies on board, they need to monitor the</p> <p>980:7 volume of controlled substances sold to</p> <p>980:8 customers."</p> <p>980:9 Does that also accurately</p> <p>980:10 reflect a registrant's duties?</p>	TP01.360
980:13 - 980:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:16)</b></p> <p>980:13 THE WITNESS: Yes.</p> <p>980:14 QUESTIONS BY MS. SINGER:</p> <p>980:15 Q. And the last sentence,</p> <p>980:16 "Subsequently, when distributors set</p> <p>980:17 thresholds for customers, they should be</p> <p>980:18 enforced. In such cases where thresholds are</p> <p>980:19 adjusted, distributors should be able to</p> <p>980:20 document the justification for these</p> <p>980:21 changes."</p> <p>980:22 Does that also accurately</p> <p>980:23 reflect a registrant's obligations?</p>	TP01.361
981:02 - 981:02	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>981:2 THE WITNESS: Yes.</p>	TP01.362
981:15 - 982:01	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b></p> <p>981:15 (Prevoznik Plaintiff's Exhibit</p> <p>981:16 P47 marked for identification.)</p> <p>981:17 QUESTIONS BY MS. SINGER:</p> <p>981:18 Q. Okay. So I want to turn to</p> <p>981:19 Exhibit 47, please.</p> <p>981:20 And that is Bates number</p> <p>981:21 PPLP0300001799742.</p> <p>981:22 If you turn to the first slide,</p> <p>981:23 it's titled "DEA/OD 11th Pharmaceutical</p> <p>981:24 Industry Conference."</p> <p>981:25 Do you recognize this</p> <p>982:1 presentation?</p>	TP01.363
982:15 - 982:20	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b></p> <p>982:15 Q. Okay. It does have on the</p> <p>982:16 front page DOJ, DEA logos, correct?</p>	TP01.364

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	982:17 A. Yes.	
	982:18 Q. Okay. And does it look -- from	
	982:19 your knowledge, is this a presentation by the	
	982:20 DEA?	
982:23 - 983:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:44)</b>	TP01.365
	982:23 THE WITNESS: Yes.	
	982:24 QUESTIONS BY MS. SINGER:	
	982:25 Q. Okay. And if you turn to the	
	983:1 fifth page, with the slide "retail	
	983:2 diversion," 90 percent at doctor, pharmacy,	
	983:3 hospital levels.	
	983:4 Do you see that slide?	
	983:5 A. Yes.	
	983:6 Q. Okay. And if you look at the	
	983:7 notes that are at the bottom of that slide,	
	983:8 do you see the bottom section that starts,	
	983:9 "Estimated 1.5 percent of doctors are	
	983:10 negligent and/or dishonest"?	
	983:11 Do you see where I'm reading?	
	983:12 A. Yes.	
	983:13 Q. Okay. It says, "That portion	
	983:14 of DEA-registered physicians is many	
	983:15 thousands. Their CS, or controlled	
	983:16 substance, prescribing would total hundreds	
	983:17 of thousands of scripts/millions of dosage	
	983:18 units into illicit market."	
	983:19 Is that accurate?	
983:25 - 984:05	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.366
	983:25 THE WITNESS: Yes.	
	984:1 QUESTIONS BY MS. SINGER:	
	984:2 Q. And is it true, as it says	
	984:3 here, that it is impossible for DEA to	
	984:4 investigate and discipline that number of	
	984:5 professionals?	
984:09 - 984:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.367
	984:9 THE WITNESS: I mean, we do the	
	984:10 best we can.	
	984:11 QUESTIONS BY MS. SINGER:	
	984:12 Q. But that's a lot of --	
	984:13 A. It's a lot.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
984:17 - 984:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b> 984:17 Q. And the last line here, "Far 984:18 more effective, address the risk at the apex 984:19 of the distribution center [sic]." 984:20 Is that accurate, that that is 984:21 a more effective way of enforcing compliance 984:22 with the Controlled Substances Act?	TP01.368
985:02 - 985:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b> 985:2 Q. Or an important tool for the 985:3 DEA?	TP01.369
985:06 - 985:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:16)</b> 985:6 THE WITNESS: Yes. 985:7 QUESTIONS BY MS. SINGER: 985:8 Q. Okay. And in fact, that's part 985:9 of the foundation of the Controlled 985:10 Substances Act, that each participant in the 985:11 supply chain has to police its own 985:12 participation in that supply chain, correct?	TP01.370
985:16 - 985:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 985:16 THE WITNESS: Yes.	TP01.371
986:09 - 987:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:55)</b> 986:9 All right. I'm showing you 986:10 Exhibit 48. And the level -- and I'm sorry, 986:11 this is CAH_MDL2804_00889528. 986:12 Do you recognize the logo on 986:13 the front of this presentation? 986:14 A. Yes. 986:15 Q. And what is it? 986:16 A. It's our Chief Counsel's logo. 986:17 Q. Okay. And if you turn to the 986:18 inside first page, How to Keep Or Lose Your 986:19 DEA Registration, do you recognize this 986:20 presentation? 986:21 A. Yes. 986:22 Q. And what do you recognize it to 986:23 be? 986:24 A. It was one of the -- it was -- 986:25 it was given at a conference that we held. 987:1 Q. A conference -- 987:2 A. For the industry.	TP01.372

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
987:3	Q. Okay. A conference that DEA	
987:4	had for industry?	
987:5	A. Yes.	
987:6	Q. And do you know who gave this	
987:7	presentation?	
987:08 - 987:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	TP01.373
987:8	Do you know if would have been	
987:9	Linden Barber?	
987:12 - 988:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:36)</b>	TP01.374
987:12	THE WITNESS: I believe it was	
987:13	Linden that gave this.	
987:14	QUESTIONS BY MS. SINGER:	
987:15	Q. Okay. And Linden Barber was	
987:16	with the Chief Counsel's Office of DEA,	
987:17	correct?	
987:18	A. Yes.	
987:19	Q. Okay. And if you turn to	
987:20	page 4 of the presentation, titled "Effective	
987:21	Controls Against Diversion," the first point	
987:22	there is what, the first bullet point?	
987:23	A. "Good recordkeeping is	
987:24	essential."	
987:25	Q. Do you agree with that	
988:1	statement?	
988:2	A. Yes.	
988:3	Q. In DEA's experience, is the	
988:4	absence of documentation a fairly good	
988:5	indication that something didn't happen in a	
988:6	registrant's compliance program?	
988:09 - 988:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.375
988:9	THE WITNESS: Yes.	
988:11 - 988:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:24)</b>	TP01.376
988:11	Q. Okay. Turning to page 9, this	
988:12	is what doesn't work, or how to lose your DEA	
988:13	registration.	
988:14	The second bullet point, what	
988:15	does that say?	
988:16	A. "It is not my job to	
988:17	second-guess the doctor."	
988:18	Q. Okay. And that's not an excuse	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

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988:23 - 989:03	<p>988:19 that the DEA will accept from a registrant, 988:20 correct?</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>988:23 THE WITNESS: Yes. 988:24 QUESTIONS BY MS. SINGER: 988:25 Q. And that's because it's a 989:1 registrant's responsibility to act on 989:2 information that points to diversion, 989:3 correct?</p>	TP01.377
989:06 - 989:12	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b></p> <p>989:6 THE WITNESS: Correct. 989:7 QUESTIONS BY MS. SINGER: 989:8 Q. And it's not that the 989:9 registrant is being asked to judge a 989:10 prescription or a patient, but to look at red 989:11 flags like the volume or dose or appearance 989:12 of a practice, et cetera, correct?</p>	TP01.378
989:16 - 989:24	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b></p> <p>989:16 THE WITNESS: Yes, they should 989:17 look into totality of everything 989:18 that's presented to them. 989:19 QUESTIONS BY MS. SINGER: 989:20 Q. Okay. And the last excuse on 989:21 this slide, "I'm not responsible for what my 989:22 customer does with the drugs." 989:23 Is that an excuse that the DEA 989:24 accepts from a registrant?</p>	TP01.379
990:02 - 990:06	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>990:2 THE WITNESS: No. 990:3 QUESTIONS BY MS. SINGER: 990:4 Q. And that's because a registrant 990:5 is responsible to make sure that they are not 990:6 supplying to potential diversion, correct?</p>	TP01.380
990:10 - 990:10	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>990:10 THE WITNESS: Correct.</p>	TP01.381
992:08 - 992:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b></p> <p>992:8 Q. Okay. And then it goes on to 992:9 say, "Know your customers and, where 992:10 applicable, the prescriber's business or 992:11 professional practice."</p>	TP01.382

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	992:12 Is that also the DEA's guidance	
	992:13 to industry as to what's required?	
	992:14 A. Yes.	
	992:15 Q. And "know the statutory	
	992:16 factors, the DEA's final orders," and then	
	992:17 lastly, "act consistently with DEA's goal:	
	992:18 protect the public health and safety from the	
	992:19 harms caused by diversion."	
	992:20 Is that also the guidance that	
	992:21 DEA gave to industry about complying with the	
	992:22 Controlled Substances Act?	
	992:23 A. Yes.	
992:25 - 993:01	<b>Prevoznik, Thomas 05-17-2019 (00:00:00)</b>	TP01.383
	992:25 (Prevoznik Plaintiff's Exhibit	
	993:1 P49 marked for identification.)	
997:14 - 997:16	<b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b>	TP01.384
	997:14 Q. Would DEA agree that a	
	997:15 significant increase in a prescriber's volume	
	997:16 is a sign of potential diversion?	
997:19 - 997:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b>	TP01.385
	997:19 THE WITNESS: Just volume	
	997:20 alone?	
	997:21 QUESTIONS BY MS. SINGER:	
	997:22 Q. That it is one sign of	
	997:23 potential diversion, yes.	
	997:24 A. It --	
998:02 - 998:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b>	TP01.386
	998:2 THE WITNESS: Potentially, yes.	
	998:3 QUESTIONS BY MS. SINGER:	
	998:4 Q. Okay. And that a prescriber	
	998:5 who is prescribing at very high volume	
	998:6 relative to other practitioners, that would	
	998:7 also be another potential red flag of	
	998:8 diversion, correct?	
998:13 - 998:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:16)</b>	TP01.387
	998:13 THE WITNESS: It could be. It	
	998:14 just depends on what is the	
	998:15 physician's practice; does he	
	998:16 specialize in end of life or something	
	998:17 like that. I mean, you'd have to take	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	998:18 in other factors.	
	998:19 QUESTIONS BY MS. SINGER:	
	998:20 Q. Right. You have to look at the	
	998:21 whole picture.	
	998:22 But that's one sign that might	
	998:23 alert you to take a closer look, correct?	
	998:24 A. Correct.	
999:03 - 999:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.388
	999:3 Q. And if the prescriber is	
	999:4 prescribing at very high doses, again, one	
	999:5 factor, depending on their specialty and	
	999:6 patients, that might alert a registrant to	
	999:7 potential diversion, correct?	
999:12 - 999:12	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.389
	999:12 THE WITNESS: Correct.	
999:25 - 1000:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	TP01.390
	999:25 Q. These are the kinds of	
	1000:1 commonsense red flags that a registrant	
	1000:2 should know to apply in looking for diversion	
	1000:3 without the DEA telling them specifically to	
	1000:4 look for them, correct?	
1000:06 - 1000:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.391
	1000:6 THE WITNESS: Yes.	
1007:11 - 1007:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b>	TP01.392
	1007:11 Q. Now, does the fact that there	
	1007:12 are bad doctors who are writing illegitimate	
	1007:13 prescriptions or pharmacies that are	
	1007:14 dispensing illegally relieve distributors or	
	1007:15 manufacturers of their duty to review their	
	1007:16 own information and data for suspicious	
	1007:17 orders and signs of diversion?	
1007:24 - 1007:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.393
	1007:24 THE WITNESS: No.	
1008:02 - 1008:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>	TP01.394
	1008:2 Q. And in fact, in a closed	
	1008:3 system, the participants in the supply chain,	
	1008:4 those who are on the inside, have a duty to	
	1008:5 look out for bad doctors and bad pharmacies,	
	1008:6 correct?	
1008:10 - 1008:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.395

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1010:01 - 1010:09	<p>1008:10 THE WITNESS: Yes.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:22)</b></p> <p>1010:1 Q. Now, you talked about the fact</p> <p>1010:2 that DEA doesn't set a formula or a threshold</p> <p>1010:3 for industry to apply, correct?</p> <p>1010:4 A. Correct.</p> <p>1010:5 Q. And is that -- is the reason</p> <p>1010:6 for that because the DEA wouldn't necessarily</p> <p>1010:7 be able to capture what the industry knows</p> <p>1010:8 about its own customers in setting a</p> <p>1010:9 threshold?</p>	TP01.465
1010:12 - 1011:02	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:34)</b></p> <p>1010:12 THE WITNESS: I think it's</p> <p>1010:13 part -- a part of -- certainly that's</p> <p>1010:14 part of it, but the other part would</p> <p>1010:15 also be we don't regulate the practice</p> <p>1010:16 of medicine, so we're not interfering</p> <p>1010:17 with what doctors are doing to treat</p> <p>1010:18 their patients.</p> <p>1010:19 So in discussions with -- when</p> <p>1010:20 these thresholds and things -- it also</p> <p>1010:21 affects the opposite side. So it's</p> <p>1010:22 not only the diverted side, but it's</p> <p>1010:23 also legitimate patients who can't get</p> <p>1010:24 them because of these thresholds that</p> <p>1010:25 are in place. So it's affecting both</p> <p>1011:1 sides of the -- it's a delicate</p> <p>1011:2 balance.</p>	TP01.466
1011:11 - 1011:14	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b></p> <p>1011:11 Q. Okay. And the danger is if the</p> <p>1011:12 DEA were to set the threshold too high, it</p> <p>1011:13 wouldn't be a real check on identifying</p> <p>1011:14 suspicious orders, correct?</p>	TP01.396
1011:18 - 1011:22	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b></p> <p>1011:18 THE WITNESS: Yes.</p> <p>1011:19 QUESTIONS BY MS. SINGER:</p> <p>1011:20 Q. And if you set it too low, as</p> <p>1011:21 you said, patients might not be able to get</p> <p>1011:22 medicine they need, correct?</p>	TP01.397
1012:01 - 1012:01	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p>	TP01.398



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1012:03 - 1012:07	1012:1 THE WITNESS: Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	TP01.399
1012:10 - 1012:11	1012:3 Q. And so it's not that the DEA 1012:4 has some answer on what the threshold should 1012:5 be and isn't telling industry; it's that the 1012:6 DEA is actually saying that industry knows 1012:7 better from its own customers, correct? <b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	TP01.400
1012:15 - 1012:16	1012:10 THE WITNESS: They're in a 1012:11 better position than we are. <b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.401
1012:17 - 1014:01	1012:15 Q. Okay. So let's go to -- I'm 1012:16 showing you Exhibit 54. <b>Prevoznik, Thomas 05-17-2019 (00:01:19)</b> 1012:17 So do you recognize 1012:18 MNK-T1_0008504654? 1012:19 A. I recognize the names. 1012:20 Q. Okay. Which names do you 1012:21 recognize? 1012:22 A. Mark Caverly and James 1012:23 Crawford. 1012:24 Q. And who are they? 1012:25 A. Former employees of DEA. 1013:1 Q. Okay. And it says -- if you 1013:2 look down this document, you see 1013:3 Mr. Crawford, I think, three paragraphs from 1013:4 the bottom. Okay. I'm sorry, let's go up 1013:5 from that to the question. 1013:6 "During the distributor 1013:7 breakout session, suspicious order monitoring 1013:8 was certainly a hotbed of discussion. Are 1013:9 there any plans for DEA to publicize 1013:10 information to implement SOM, or suspicious 1013:11 order monitoring, incorporate algorithms 1013:12 where products are more likely to be 1013:13 diverted?" 1013:14 Do you see where I'm reading? 1013:15 A. Yes. 1013:16 Q. Okay. And then can you read 1013:17 Mr. Crawford's response?	TP01.402

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1013:18	A. "Whatever we put out will be	
1013:19	outdated by the time we put it out. You're	
1013:20	looking at a number. Tell me how much --	
1013:21	tell me how much that we can't exceed. DEA	
1013:22	can't do that. It's part of your due	
1013:23	diligence, knowing your customer."	
1013:24	Q. And does that reflect what you	
1013:25	just testified to in the guidance that DEA	
1014:1	gave industry?	
1014:02 - 1014:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.403
1014:2	A. Yes.	
1015:03 - 1015:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:23)</b>	TP01.404
1015:3	Q. Okay. Showing you Exhibit 55.	
1015:4	My goal here is to make your pile go up and	
1015:5	mine go down.	
1015:6	All right. This is	
1015:7	MCKMDL00561303, executive summary regarding	
1015:8	the HDMA document.	
1015:9	Have you seen this document	
1015:10	before, Mr. Prevoznik?	
1015:11 - 1015:23	<b>Prevoznik, Thomas 05-17-2019 (00:00:35)</b>	TP01.405
1015:11	A. I'm not sure.	
1015:12	Q. Okay. Let me direct you to the	
1015:13	last page, Bates number 306. It says in that	
1015:14	top bullet to question 10, "This is another	
1015:15	area that we have made great strides in over	
1015:16	the past few years. Our analytical	
1015:17	capabilities provide us with greater insight	
1015:18	into our own customer base. We have this	
1015:19	data already and frankly are in a position to	
1015:20	provide better information to DEA than they	
1015:21	could provide to us."	
1015:22	Does DEA agree with that	
1015:23	statement?	
1016:01 - 1016:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b>	TP01.406
1016:1	THE WITNESS: Yes.	
1016:2	QUESTIONS BY MS. SINGER:	
1016:3	Q. And it says as a sidenote, "DEA	
1016:4	does not have dispensing data, nor do they	
1016:5	have noncontrol data," correct?	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1016:6	A. Correct.	
1017:01 - 1017:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:23)</b>	TP01.407
1017:1	Q. Based on your experience	
1017:2	in all of your years at DEA in management and	
1017:3	as a diversion investigator and as the	
1017:4	representative of the DEA here today, did DEA	
1017:5	make the best judgments it could at the time	
1017:6	to use your authority and resources most	
1017:7	effectively to prevent diversion?	
1017:13 - 1017:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.408
1017:13	THE WITNESS: Yes, I think we	
1017:14	did.	
1017:16 - 1017:20	<b>Prevoznik, Thomas 05-17-2019 (00:00:13)</b>	TP01.409
1017:16	Q. Had distributors reported	
1017:17	suspicious orders to the DEA as the law	
1017:18	required would DEA have been able to use its	
1017:19	resources more effectively to identify and	
1017:20	prevent diversion?	
1018:03 - 1018:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.410
1018:3	THE WITNESS: I believe so.	
1018:11 - 1018:14	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	TP01.411
1018:11	Q. Okay. And if registrants had	
1018:12	reported suspicious orders to the DEA, does	
1018:13	the DEA believe that there would have been	
1018:14	less diversion, less abuse and less death?	
1018:21 - 1018:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.412
1018:21	THE WITNESS: Yes.	
1022:13 - 1022:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:36)</b>	TP01.413
1022:13	Q. I'm going to show you	
1022:14	Exhibit 56.	
1022:15	Mr. Prevoznik, this is our	
1022:16	effort to put in a timeline the actions DEA	
1022:17	took against defendants in this litigation.	
1022:18	Does this capture the major	
1022:19	enforcement initiatives that DEA took against	
1022:20	distributors, manufacturers and distributors,	
1022:21	including pharmacies?	
1025:24 - 1026:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:29)</b>	TP01.414
1025:24	THE WITNESS: Yeah.	
1025:25	It appears to have most of the	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	1026:1 highlights.	
	1026:2 QUESTIONS BY MS. SINGER:	
	1026:3 Q. Okay. And is it fair to say	
	1026:4 that the DEA has investigated or taken action	
	1026:5 against virtually every major distributor of	
	1026:6 opioids over the last 15 years?	
1026:09 - 1026:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.415
	1026:9 THE WITNESS: Yes.	
1026:12 - 1026:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.467
	1026:12 Q. And also the major pharmacy	
	1026:13 chains that distribute opioids?	
1026:15 - 1026:18	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.468
	1026:15 THE WITNESS: Yes.	
	1026:16 QUESTIONS BY MS. SINGER:	
	1026:17 Q. And also manufacturers like	
	1026:18 Mallinckrodt and Purdue, correct?	
1026:20 - 1026:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b>	TP01.469
	1026:20 THE WITNESS: Correct.	
	1026:21 QUESTIONS BY MS. SINGER:	
	1026:22 Q. Now, this chart doesn't reflect	
	1026:23 additional actions that the DEA took against	
	1026:24 doctors and pharmacists, correct?	
1027:03 - 1027:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.470
	1027:3 THE WITNESS: Yes.	
	1027:4 QUESTIONS BY MS. SINGER:	
	1027:5 Q. Or actions you took against	
	1027:6 independent pharmacies.	
	1027:7 And I take it the DEA also took	
	1027:8 enforcement action against non-chain	
	1027:9 pharmacies, correct?	
1027:17 - 1027:22	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b>	TP01.471
	1027:17 THE WITNESS: Yes. In my	
	1027:18 personal capacity, yes, we would.	
	1027:19 QUESTIONS BY MS. SINGER:	
	1027:20 Q. Okay. So this isn't everything	
	1027:21 the DEA did in this time period, correct?	
	1027:22 A. Correct.	
1028:05 - 1028:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.416
	1028:5 Q. Okay. Now, isn't it true that	
	1028:6 even without information on a competitor's	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1028:11 - 1028:25	<p>1028:7 orders, that registrants can identify  1028:8 suspicious orders and potential diversion?  <b>Prevoznik, Thomas 05-17-2019 (00:00:20)</b>  1028:11 THE WITNESS: So essentially  1028:12 their own data.  1028:13 QUESTIONS BY MS. SINGER:  1028:14 Q. Yes.  1028:15 A. Yes.  1028:16 Q. Okay. And when you've taken --  1028:17 when you, the DEA, has taken enforcement  1028:18 actions or entered into settlement agreements  1028:19 with registrants, you've looked at their own  1028:20 data, correct?  1028:21 A. Yes.  1028:22 Q. And what those registrants  1028:23 should have known or did know about their own  1028:24 customers, correct?  1028:25 A. Correct.</p>	TP01.417
1029:04 - 1029:06	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>  1029:4 Q. And you haven't taken those  1029:5 actions based on data from other registrants,  1029:6 correct?</p>	TP01.418
1029:09 - 1029:09	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:00)</b>  1029:9 THE WITNESS: Correct.</p>	TP01.419
1029:12 - 1029:16	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>  1029:12 So just to be perfectly clear,  1029:13 you didn't expect Cardinal to know what  1029:14 McKesson or AmerisourceBergen was supplying  1029:15 to a customer, correct?  1029:16 A. Correct.</p>	TP01.420
1029:19 - 1029:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>  1029:19 Q. Is it the DEA's experience that  1029:20 suspicious orders filled by manufacturers,  1029:21 distributors and pharmacies were suspicious  1029:22 in their own right without anybody else's  1029:23 data?</p>	TP01.421
1030:03 - 1030:08	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:10)</b>  1030:3 THE WITNESS: Yes.  1030:4 QUESTIONS BY MS. SINGER:  1030:5 Q. And when distributors take on</p>	TP01.422

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1030:11 - 1030:11	1030:6 or registrants take on a new customer, DEA 1030:7 recommends that they ask whether that 1030:8 customer uses other distributors, correct? <b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.423
1030:18 - 1030:21	1030:11 THE WITNESS: Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1030:18 DEA also recommends that a 1030:19 distributor obtain dispensing data from a 1030:20 pharmacy before they take them on as a 1030:21 customer, correct?	TP01.424
1030:24 - 1030:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 1030:24 THE WITNESS: Yes, if they can 1030:25 get it.	TP01.425
1032:15 - 1032:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:12)</b> 1032:15 Q. Now, if a pharmacy won't 1032:16 provide dispensing information to a 1032:17 distributor, would that be a red flag that 1032:18 the distributor needs to look more closely at 1032:19 that customer?	TP01.426
1033:03 - 1033:04	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 1033:3 THE WITNESS: Yes, they should 1033:4 be.	TP01.427
1033:08 - 1033:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b> 1033:8 Q. A distributor should ask? 1033:9 A. Should ask for it.	TP01.428
1034:04 - 1034:07	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1034:4 Q. Now, distributors have 1034:5 information on both controlled and 1034:6 noncontrolled substances that are ordered by 1034:7 a customer, correct?	TP01.429
1034:10 - 1034:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 1034:10 THE WITNESS: Yes.	TP01.430
1034:12 - 1034:15	<b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b> 1034:12 Q. And that lets them see where a 1034:13 customer's order of controlled substances is 1034:14 disproportionate to its other orders, 1034:15 correct?	TP01.431
1034:19 - 1034:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b> 1034:19 THE WITNESS: Yes.	TP01.432
1034:21 - 1034:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	TP01.433

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1034:21	Q. And so if a customer is	
1034:22	ordering a lot of opioids and very little	
1034:23	antibiotics or diabetes medicine, that would	
1034:24	be one potential red flag of diversion,	
1034:25	correct?	
1035:04 - 1035:13	<b>Prevoznik, Thomas 05-17-2019 (00:00:16)</b>	TP01.434
1035:4	THE WITNESS: Yes, it could	
1035:5	potentially be a red flag.	
1035:6	QUESTIONS BY MS. SINGER:	
1035:7	Q. A red flag?	
1035:8	A. Yes.	
1035:9	Q. Okay. And it's also true that	
1035:10	pharmacies that order a certain mix of drugs	
1035:11	that are abused together, that that can be	
1035:12	another red flag of potential diversion,	
1035:13	correct?	
1035:17 - 1035:21	<b>Prevoznik, Thomas 05-17-2019 (00:00:08)</b>	TP01.435
1035:17	THE WITNESS: Yes.	
1035:18	QUESTIONS BY MS. SINGER:	
1035:19	Q. Now, distributors have that	
1035:20	data on other noncontrolled substance orders,	
1035:21	correct?	
1036:01 - 1036:06	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	TP01.436
1036:1	THE WITNESS: Yes.	
1036:2	QUESTIONS BY MS. SINGER:	
1036:3	Q. But DEA doesn't get reporting	
1036:4	from distributors on noncontrolled substances	
1036:5	ordered by customers, correct?	
1036:6	A. No, we do not.	
1037:09 - 1037:10	<b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.437
1037:9	Q. And DEA doesn't have	
1037:10	prescribing information in ARCOS, correct?	
1037:13 - 1037:17	<b>Prevoznik, Thomas 05-17-2019 (00:00:06)</b>	TP01.438
1037:13	THE WITNESS: Correct.	
1037:14	QUESTIONS BY MS. SINGER:	
1037:15	Q. But that information is	
1037:16	certainly useful in detecting suspicious	
1037:17	orders or potential diversion, correct?	
1037:20 - 1037:25	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	TP01.439
1037:20	THE WITNESS: Correct.	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1037:21	QUESTIONS BY MS. SINGER:	
1037:22	Q. Is DEA aware that registrants	
1037:23	have information -- have access to	
1037:24	information on cash payments that are	
1037:25	received by pharmacies?	
1038:05 - 1038:11	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.440
1038:5	THE WITNESS: I believe we do.	
1038:6	I believe they do.	
1038:7	QUESTIONS BY MS. SINGER:	
1038:8	Q. They do?	
1038:9	A. Yeah.	
1038:10	Q. And does DEA have that	
1038:11	information?	
1038:13 - 1039:05	<b>Prevoznik, Thomas 05-17-2019 (00:00:32)</b>	TP01.441
1038:13	THE WITNESS: If we subpoena	
1038:14	it.	
1038:15	QUESTIONS BY MS. SINGER:	
1038:16	Q. Okay. But not in the regular	
1038:17	course --	
1038:18	A. No.	
1038:19	Q. -- of identifying potential	
1038:20	diversion?	
1038:21	A. Right.	
1038:22	Q. Now, does ARCOS data tell you	
1038:23	whether a customer is near a hospital or a	
1038:24	cancer center or a hospice treatment	
1038:25	facility?	
1039:1	A. No, it's just transactional	
1039:2	data.	
1039:3	Q. Okay. But distributors and	
1039:4	manufacturers would learn that information in	
1039:5	their due diligence on customers, correct?	
1039:08 - 1039:08	<b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.442
1039:8	THE WITNESS: Yes.	
1039:22 - 1040:02	<b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	TP01.443
1039:22	Q. So when you get, you know, a	
1039:23	big stack of excess order reports or	
1039:24	ingredient limit reports, you can't tell if a	
1039:25	large order is from a customer that's near an	
1040:1	oncology center or a hospital, for instance,	



## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1040:05 - 1040:06	1040:2 correct? <b>Prevoznik, Thomas 05-17-2019 (00:00:02)</b>	TP01.444
1043:02 - 1043:05	1040:5 THE WITNESS: Correct. From 1040:6 the reports, you cannot. <b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b>	TP01.445
1045:07 - 1045:11	1043:2 Q. And is it the DEA's experience 1043:3 that registrants have objected to sharing 1043:4 ARCOS data with their competitors? 1043:5 A. Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.446
1045:14 - 1045:17	1045:7 Q. And if a registrant has 1045:8 information that would alert it to diversion, 1045:9 it has an obligation under the Controlled 1045:10 Substances Act to use that information to 1045:11 prevent diversion, correct? <b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.447
1045:19 - 1045:21	1045:14 THE WITNESS: Correct. 1045:15 QUESTIONS BY MS. SINGER: 1045:16 Q. And you can't be like that 1045:17 monkey, hiding your eyes -- <b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b>	TP01.448
1045:23 - 1046:01	1045:19 QUESTIONS BY MS. SINGER: 1045:20 Q. -- and say, "We only use that 1045:21 data for marketing" -- <b>Prevoznik, Thomas 05-17-2019 (00:00:04)</b>	TP01.449
1046:03 - 1046:03	1045:23 QUESTIONS BY MS. SINGER: 1045:24 Q. -- "or accounting." 1045:25 You have to use that data for 1046:1 compliance, too, correct? <b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b>	TP01.450
1051:09 - 1051:14	1046:3 THE WITNESS: Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b>	TP01.451
1052:05 - 1052:07	1051:9 Q. In that last sentence that 1051:10 "chain store due diligence reviews must not 1051:11 be treated any differently than independent 1051:12 retail pharmacy customers," does that 1051:13 represent the view of the DEA? 1051:14 A. Yes. <b>Prevoznik, Thomas 05-17-2019 (00:00:03)</b>	TP01.452
	1052:5 That's the guidance that DEA	

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
1052:08 - 1052:11	<p>1052:6 gave to registrants?</p> <p>1052:7 A. Correct.</p> <p><b>Prevoznik, Thomas 05-17-2019 (00:00:15)</b></p> <p>1052:8 Q. All right. Should distributors</p> <p>1052:9 be looking at all of the volume of opioids</p> <p>1052:10 they supply into a geographic area in</p> <p>1052:11 determining whether orders may be suspicious?</p>	TP01.453
1052:15 - 1052:22	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:11)</b></p> <p>1052:15 THE WITNESS: It would</p> <p>1052:16 definitely help.</p> <p>1052:17 QUESTIONS BY MS. SINGER:</p> <p>1052:18 Q. Okay. Meaning if they're</p> <p>1052:19 supplying in ways that are very</p> <p>1052:20 disproportionate to the population, that</p> <p>1052:21 should be a sign that they're not supplying</p> <p>1052:22 to a legitimate market, correct?</p>	TP01.454
1052:25 - 1053:05	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:07)</b></p> <p>1052:25 THE WITNESS: Correct.</p> <p>1053:1 QUESTIONS BY MS. SINGER:</p> <p>1053:2 Q. And distributors may not know</p> <p>1053:3 all of the pills that are going into an area,</p> <p>1053:4 but they certainly know what pills they're</p> <p>1053:5 sending, correct?</p>	TP01.455
1053:11 - 1053:11	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:01)</b></p> <p>1053:11 THE WITNESS: Correct.</p>	TP01.456
1054:16 - 1054:23	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:21)</b></p> <p>1054:16 Q. Let me do it as an</p> <p>1054:17 example.</p> <p>1054:18 If the threshold says that an</p> <p>1054:19 order of 10,000 dosage units exceeds</p> <p>1054:20 threshold and a customer orders 50,000 dosage</p> <p>1054:21 units, can the distributor just cut the order</p> <p>1054:22 to 10,000 units and ship it without</p> <p>1054:23 investigating whether it's suspicious or not?</p>	TP01.457
1055:02 - 1055:12	<p><b>Prevoznik, Thomas 05-17-2019 (00:00:19)</b></p> <p>1055:2 THE WITNESS: Well, in your</p> <p>1055:3 hypothetical it sounded like it was</p> <p>1055:4 already triggered as a suspicious</p> <p>1055:5 order, so immediately upon discovery</p> <p>1055:6 they were supposed to tell us anyway</p>	TP01.458

## TP01-Prevoznik, Thomas - Plaintiffs' Submission

Page/Line	Source	ID
	1055:7 that this happened.	
	1055:8 QUESTIONS BY MS. SINGER:	
	1055:9 Q. And shipping less of it doesn't	
	1055:10 make it not suspicious anymore. If it's a	
	1055:11 suspicious order, it's a suspicious order,	
	1055:12 correct?	
1055:15 - 1055:19	<b>Prevoznik, Thomas 05-17-2019 (00:00:09)</b>	TP01.459
	1055:15 THE WITNESS: Right. So they	
	1055:16 can either not ship it or they can	
	1055:17 investigate to determine -- to	
	1055:18 alleviate the suspicions that they	
	1055:19 have.	
1056:19 - 1056:24	<b>Prevoznik, Thomas 05-17-2019 (00:00:14)</b>	TP01.460
	1056:19 Under the title "Ensuring	
	1056:20 Patient Access and Effective Drug Enforcement	
	1056:21 Act," first sentence, "The United States is	
	1056:22 currently facing an opioid epidemic."	
	1056:23 Is that the view of the DEA?	
	1056:24 A. Yes.	
1262:07 - 1262:09	<b>Prevoznik, Thomas 05-17-2019 (00:00:05)</b>	TP01.461
	1262:7 Q. Okay. You didn't want to sit	
	1262:8 down with HDMA to help the public?	
	1262:9 A. No.	
1262:13 - 1263:03	<b>Prevoznik, Thomas 05-17-2019 (00:00:30)</b>	TP01.462
	1262:13 THE WITNESS: No, we sat	
	1262:14 with -- we did the distributor	
	1262:15 initiative because of what we saw, and	
	1262:16 we saw that the registrants needed to	
	1262:17 be -- have -- to sit down with the	
	1262:18 registrants, talk to them and go over	
	1262:19 their own data with them to show the	
	1262:20 anomalies that are going on, in the	
	1262:21 hope that they would stop what they	
	1262:22 were doing.	
	1262:23 They said they were going to	
	1262:24 fix it; they didn't fix it. So we	
	1262:25 weren't going to go to a trade	
	1263:1 association if the registrant isn't	
	1263:2 going to fix their own internal system	
	1263:3 that they have.	

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Plaintiff Affirmatives = 02:05:49

Defense Completeness Counters = 00:02:38

**Total Time = 02:08:28**